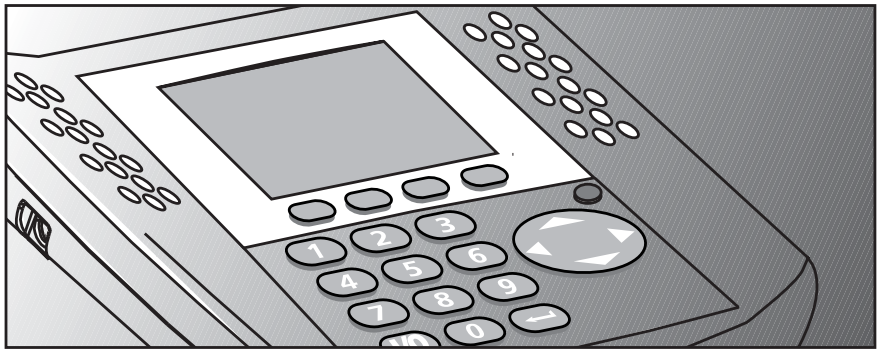
PURITAN
BENNETT

Renaissance® II



Spirometry System
User's Manual

WARNING

The user should read and understand all product literature, labeling and warnings prior to operating the Renaissance II Spirometry System

To obtain information about warranty for this product contact
Puritan Bennett Technical Support at:
1-800-255-6774

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Listing of Warnings, Cautions, and Notes

Throughout this manual there are three indicators to convey information of a specific nature. These indicators are warnings, cautions and notes. Carefully read and understand these notices as they relate to adjacent text.

WARNING

Warnings alert the user to potential serious outcomes (death, injury, or adverse events) to the patient or user.

CAUTION:
Cautions alert the user to exercise care necessary for the safe and effective use of the Renaissance II Spirometry System.

NOTE: Indicates points of particular emphasis that make operation of the spirometer more efficient or convenient.

WARNING

The user should read and understand all product literature, labeling and warnings prior to operating the Renaissance II Spirometry System.

Patient Safety Warnings

- ***This device should be used by trained healthcare professionals and is not intended for patient operation.***
- ***Physicians should assess patient's ability to perform spirometry testing prior to administering the test.***
- ***Patient fainting or falling due to dizziness may occur as a result of this test. Advise the patient to sit or stand comfortably near a chair during test.***

Patient Data Warnings

- ***Predicted values will be extrapolated for patients with age or height outside the age and/or height limits supported by the selected author's normal equations.***
- ***Results from spirometry testing should not be the sole source for determining a patient's diagnosis and treatment. Other clinical data, such as patient symptoms and respiratory history, should always be considered.***

Use Environment Warnings

- ***The Renaissance II Spirometry System is not intended for use in an oxygen-enriched atmosphere or in the presence of flammable anesthetics.***
- ***To avoid risk of electrical shock, this unit should only be used in dry locations.***

Equipment Setup Warnings

- ***As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.***
- ***When connecting the Renaissance II spirometer to any instrument, verify proper operation. Accessory equipment connected to the data interface must be certified according to IEC Standard 950 for data processing equipment or IEC Standard 601-1 for electromedical equipment. All combinations of equipment must be in compliance with IEC Standard 601-1-1 systems requirements. Anyone who connects additional equipment to the signal input port or signal output port, configures a medical system and is therefore responsible that the system complies with the requirements of IEC Standard 601-1-1 and the electromagnetic requirements of IEC Standard 601-1-2.***

WARNING

User Warnings

- ***Chemicals from a broken LCD display panel are toxic when ingested. Use caution when handling a Renaissance II spirometer with a broken display panel.***

Flow Sensor Warnings

- ***Carefully read the flow sensor directions before use, including all warnings, cautions, and instructions.***
- ***User should visually inspect the FSII sensor for loose particles/foreign materials prior to patient use.***

CAUTION

Federal law restricts this device to sale by, or on the order of, a physician.

Use Environment Cautions

- ***Do not use the Renaissance II Spirometry System in areas of high humidity, dust, or in extreme environments.***
- ***Place the Renaissance II Spirometry System in a secure location, where it is unlikely to drop or fall. Do not attempt to lift or carry the spirometer by the pressure tube or power cord.***
- ***The Renaissance II system may be susceptible to radio frequency interference. Refer to the electromagnetic interference section of this manual for more information.***

Equipment Setup Cautions

- ***The Renaissance II Spirometry System and base station are designed for use only with the Puritan Bennett AC adapter (P-495208-00). Do not connect AC Adapter (P-495208-00) to an original Renaissance system (PB-100/110) or damage will result. Conversely, do not connect a PB100/ PB110 AC adapter (P-062521-00) to the Renaissance II Spirometry System.***
- ***Prior to verifying calibration, visually verify that there is no foreign material in the pressure tube and that the tube is not damaged or kinked.***

CAUTION

Battery Cautions

- ***The NiCad battery pack or other batteries may discharge over time. Check batteries at least once per month for corrosion and verify batteries are fully charged. Store spirometer in base station to keep unit ready for use.***
- ***Remove batteries if spirometer will not be used for at least two weeks.***
- ***Dispose of batteries properly. Do not incinerate. Puritan Bennett recommends that customers or technical service personnel follow local governing ordinances and recycling instructions regarding disposal or recycling of batteries.***

Service Caution

- ***Do not remove the cover of the Renaissance II Spirometry System or base. Removal of the cover is permitted only by qualified service personnel. There are no user-serviceable parts inside.***
- ***Do not spray liquids on the Renaissance II System. Follow the cleaning instructions outlined in the Service and Maintenance section starting on page 49 of this manual.***

Flow Sensor Cautions

- ***Use only the FSII flow sensor specifically designed for the Renaissance II Spirometry System.***
- ***The FSII sensor is for single-patient use only. In the interest of environmental protection, dispose of all sensors and nose clips properly.***

Notes

Accuracy Notes

- ***For test accuracy, elevation must be entered.***
- ***Verify that the displayed barometric pressure is correct. If not correct, there will be an error in the inspired volume (FIVC) during an FVL maneuver of approximately -1.3% for every 1,000 feet above sea level. Refer to the System Configuration section starting on page 78 for more information. The barometric pressure displayed is based on the initial elevation setting of the spirometer. However, the barometric pressure may be changed and the spirometer will, from that point on, use the new value entered.***
- ***If you choose to obtain barometric pressure from an agency, such as the National Weather Service, verify that the value is NOT corrected to sea level.***

Notes

Calibration Notes

- ***The date of the last valid calibration check will display as part of the spirometer's initialization sequence if a calibration check has not been performed in the current calendar day.***
- ***The American Thoracic Society (ATS) recommends performing a three-speed calibration check on a daily basis.***
- ***Puritan Bennett recommends that the 3 liter calibration syringe be recertified on an annual basis.***
- ***Verify that the temperature of the room is the same as the temperature noted for the calibration test. For every degree discrepancy, there will be a corresponding 0.15% error in the test results.***
- ***Overestimation of the room temperature will cause lung volume to be underestimated by 5%; conversely, if temperature is underestimated, lung volume will be overestimated.***

Test Method Notes

- ***The "Val" (best value) method is recommended by the American Thoracic Society and mandated by NIOSH/OSHA standards and should be used for all industrial and disability testing.***
- ***If the patient test will be submitted for Social Security Disability (SSD) determinations, enter patient information prior to performing the SSD calibration verification.***
- ***Clinicians performing PFT studies should consider attending NIOSH training seminars and refresher courses to further their skills in spirometry testing and to stay current with industry standards.***

Spirometer Use Notes

- ***Demonstrating the test using your FSII sensor is strongly recommended for patients that have never performed a spirometry test before.***
- ***Obstructing sensor opening with teeth, lips, or tongue while performing the test will cause low readings.***

Notes

Battery Notes

- ***The Renaissance II base station allows interfacing to parallel printers and computers and provides an alternate means for charging the custom NiCad battery pack.***
- ***The Renaissance II Spirometry System is designed to recharge only the custom battery pack supplied with the system, and will not recharge batteries from other manufacturers.***
- ***When there is a low battery condition, the Renaissance II spirometer beeps every 30 seconds and a low battery icon is displayed.***
- ***Do not mix brands or types of batteries.***
- ***Puritan Bennett recommends replacing the NiCad battery pack at least once per year.***
- ***If the battery is removed, the unit will operate solely on AC power if connected to an electrical outlet via the AC adapter.***

Spirometer System Notes

- ***The serial numbers are located on a label affixed to the underside of the spirometer and base station. The first letter "G" represents the manufacturer. The next two numbers represent the year of manufacture. The two digits following the year represent either a base station (08) or a spirometer (07). The last five digits are sequential numbers assigned during manufacture.***
- ***Materials used to make this Renaissance II Spirometry System and accessories contain no Latex.***
- ***Replace the pressure tube every year.***
- ***The LCD panel will turn off after 5 minutes (and the unit will power off after 30 minutes) with no user input. To bring back the display before the 30-minute limit, press any key.***

Indicators, Symbols, and Icons

Renaissance II Spirometer

⚠	Attention, consult accompanying documents
IPX1	Refers to degree of protection - Drip Proof
	Type BF equipment
	Agency Certification
	Class II equipment
Rx ONLY	CAUTION: Federal Law (US) restricts this device to sale by, or on the order of, a physician
SN	Serial Number

Base Station

	Connection for a printer port
	I/O communications port
⎓ 12V	12 volt DC adapter connection

FSII Sensor

⚠	Attention, consult accompanying documents
2	Do not reuse - single patient use only
	Direction of flow through the flow sensor
CAL=233444	Bar coded calibration number
6	Recyclable plastic. The number 6 represents polystyrene.

Figure 1: Renaissance II Spirometry System Indicators, Symbols, and Icons

WARNING

⚠ ***The Renaissance II Spirometry System is not intended for use in an oxygen-enriched atmosphere or in the presence of flammable anesthetics.***

⚠ ***CAUTION:***
Federal law restricts this device to sale by or on the order of a physician.

Introduction to the Renaissance II Spirometry System

The Renaissance II Spirometry System consists of a spirometer, docking base and optional accessories, as shown in Figure 2. The Renaissance II system provides long-term data storage capacity, and when connected to a printer generates printouts of the data. Patient data can also be downloaded to a computer. The spirometer test results can be compared to any of several adult or pediatric predicted normal values. The spirometer also performs pre/post medication comparisons.

Features

- Intuitive graphical user interface.
- Graphic display for real-time viewing of Volume-Time, Flow-Volume and incentive displays.
- Automatically compares results to predicted values.
- Allows pre/post-medication comparisons.
- Provides clinical interpretations with COPD Risk and Lung Age calculations.
- Optional software allows data to be downloaded to a computer.
- Memory stores demographic information, graphical data and patient results for up to 1,000 patients.
- Operates with rechargeable NiCad batteries, alkaline batteries or an AC adapter.
- Provides printed reports when connected to a parallel printer.

CAUTION:

- ***Place the Renaissance II Spirometry System in a secure location, where it is unlikely to drop or fall. Do not attempt to lift or carry the Renaissance II spirometer by the pressure tube or power cord.***
- ***The Renaissance II system may be susceptible to radio frequency interference. Refer to the Electromagnetic Interference section on page 54 for more information.***

Intended Use

The intended use of the Renaissance II Spirometry System is as a diagnostic tool to measure the maximal volume and flow of air that can be moved in and out of a patient's lungs. The Renaissance II spirometer obtains the spirometric data by direct measurement of flow via the FSII sensor and pressure tube. The flow is then electronically integrated to obtain volume. This testing can be used for the detection, assessment and monitoring of certain lung diseases. The system is intended for use with pediatric (4 to 17 years) and adult patients (18 to 99) in hospitals, physicians' offices, laboratories, and occupational health testing environments.

Basic Spirometry System and Accessories

The Renaissance II Spirometry System is available in a variety of configurations. The basic spirometry system consists of the spirometer, base station, pressure tube, AC adapter, FSII flow sensors, syringe adapter, battery pack, nose clips and associated documentation (See Table 1).

Upon receipt of your system, verify that all required parts are present and undamaged. If any parts are missing or damaged, please contact Puritan Bennett Technical Support Department at 1-800-255-6774.

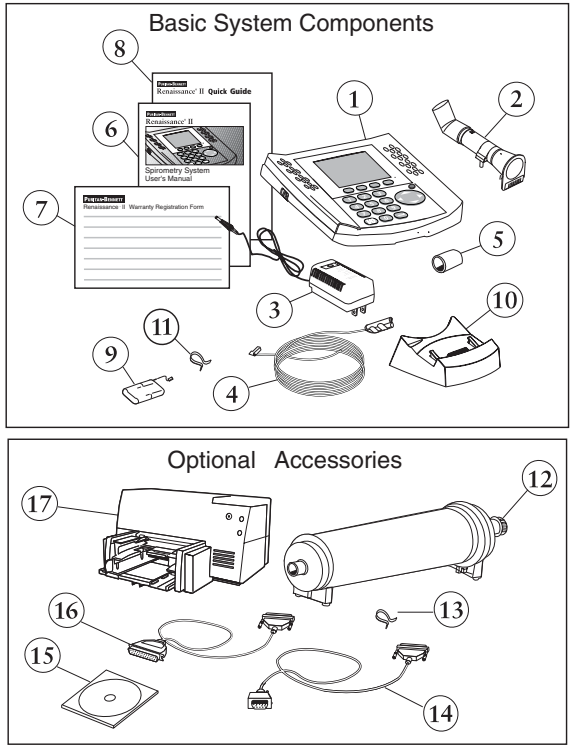


Figure 2: Renaissance II Spirometry System

Table 1: Basic Spirometry System and Accessories

1) Renaissance II Spirometer, PB-700	10) Base Station, PB-710
2) FSII Flow Sensor	11) Nose Clip, Plastic
3) AC Adapter, PB-700	*Optional Accessories*
4) Assy., Pressure Tube FSII	12) 3L Calibration Syringe
5) Syringe Adapter	13) Nose Clip, Plastic (25/pk)
6) User's Manual, PB-700/PB-710	14) Cable, Null Modem, NPB-510/PB-710
7) Warranty Card, PB-700/PB-710	15) *DataFlow*™ Data Management Software
8) Quick Guide, PB-700/PB-710	16) Cable, Printer
9) NiCad Battery Pack, PB-700	17) Printer, Spirometer Compatible

Connecting the AC Adapter

Connect the AC adapter to the 12-volt DC input jack on the side of the Renaissance II spirometer or on the rear of the base station as shown in

Figure 3. A green LED indicator will light on the front panel of the Renaissance II spirometer and on the AC adapter when properly connected to an electrical outlet.

WARNING

- ***To avoid risk of electrical shock, this unit should only be used in dry locations.***
- ***As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.***

CAUTION:
The Renaissance II Spirometry System and Base Station are designed for use only with the Puritan Bennett AC adapter (P-495208-00). Do not connect AC Adapter (P-495208-00) to an original Renaissance system (PB100/PB110) or damage will result. Conversely, do not connect a PB100/PB110 AC adapter (P-062521-00) to the Renaissance II Spirometry System.

Battery Operation

The Renaissance II spirometer includes a pre-installed rechargeable custom NiCad battery pack. As an option, the user can install 4 AA alkaline batteries or 4 standard AA NiCad cells. (Refer to *Battery Installation* on page 49 for installation instructions.) If NiCad cells are used, an external charger is required.

NOTES:

- The custom battery pack must be charged at least 24 hours before portable use.
- The Renaissance II Spirometry System is designed to recharge only the custom battery pack supplied with the system, and will not recharge batteries from other manufacturers.

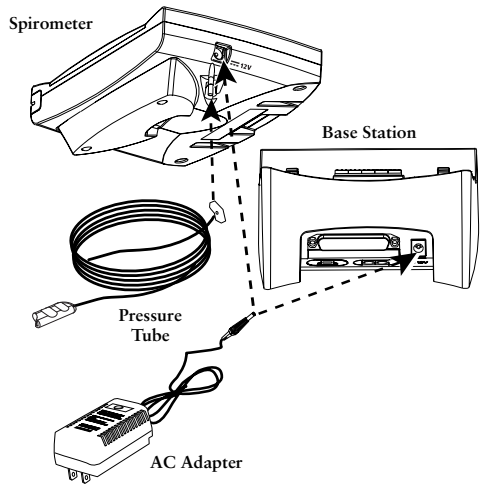


Figure 3: Setting up the System

The custom NiCad battery pack has a battery life of 10-12 hours in the ON position and a battery life of approximately 8 days in the OFF position.

The pre-installed custom NiCad battery pack will continuously charge as long as power is connected to the spirometer through the AC adapter.

During operation, the Renaissance II spirometer continually checks battery status. A low battery indicator will appear in the right hand corner of the screen when fewer than 20 patient tests can be performed. If the battery voltage drops below a reliable operating level, the unit will shut-off and not power-up until the batteries are recharged, changed, or the AC adapter is connected.

NOTE: If the battery is removed, the unit will operate solely on AC power if connected to an electrical outlet via the AC adapter.

CAUTION:

- ***The NiCad battery pack or other batteries may discharge over time. At least once per month, check batteries for corrosion and verify batteries are fully charged. Store spirometer in base station to keep unit ready for use.***
- ***Remove batteries if spirometer will not be used for at least two weeks.***

NOTE: Puritan Bennett recommends replacing the NiCad battery pack at least once per year.

Connecting the Pressure Tube

The Renaissance II spirometer is shipped with a pressure tube that connects the FSII flow sensor to the spirometer. Upon receipt, inspect the pressure tube for damage. If the tube is damaged, contact Puritan Bennett Technical Support at 1-800-255-6774.

Connect the pressure tube to the underside of the spirometer, as shown in Figure 3.

Connect the other end of the pressure tube to the FSII flow sensor, as shown in Figure 4.

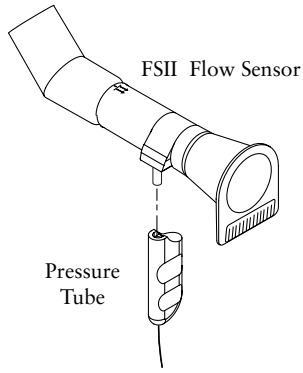


Figure 4: Connecting the Pressure tube to the FS II flow sensor

After the batteries have been installed and charged and the tube is connected, the spirometer is ready for use. The pressure tube does not need to be disconnected from the spirometer between patients.

NOTE: Replace the pressure tube every year.

Warning

- ***The Renaissance II Spirometry System is not intended for use in an oxygen-enriched atmosphere or in the presence of flammable anesthetics.***
- ***Carefully read the flow sensor directions before use, including all warnings, cautions, and instructions.***

CAUTION:
Do not spray liquids on the Renaissance II System. Follow the cleaning instructions outlined in the Service and Maintenance section starting on page 49 of this manual.

Keypad Functions and Controls

The keypad functions and controls are user friendly and intuitive. The keypad and Main screen icons, shown in Figure 5, represent some of the most frequently seen icons that will be displayed. The keypad and controls are used to access the various functions of the Renaissance II spirometer.

Main Screen Icon Features

Allows the user to enter new patient data

Begins or continues a spirometry test or allows SSD calibration

Allows the user to view the test results

Allows the user to edit previously entered patient data

Initiates one-speed spirometer calibration

Provides a variety of printed test reports

Locates a patient's previously saved test data

Allows the user to configure the spirometer

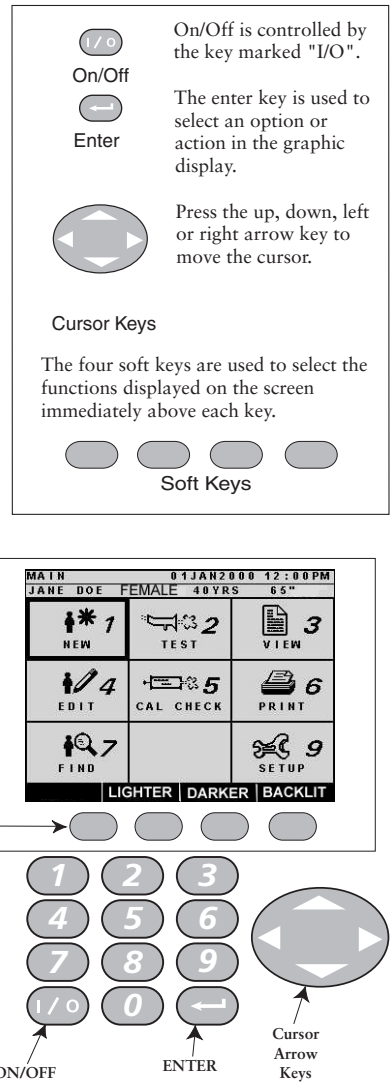


Figure 5: Keypad and Main Screen

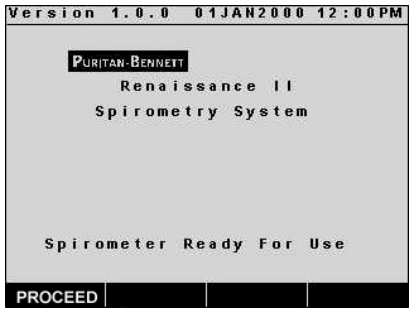


Figure 6: Ready for Use

Figure 7: Initial Setup

Initial Configuration

The Renaissance II spirometer has a number of user-selectable configuration options which have been preset at the factory. The first time the spirometer is powered on after leaving the factory, the user is prompted to select the configuration options. Refer to *System Configuration* on page 78 for a complete listing and description of the system configuration settings.

Warning

The Renaissance II Spirometry System is not intended for use in an oxygen-enriched atmosphere or in the presence of flammable anesthetics.

1. Press the I/O key to power-up the spirometer. The spirometer will display an introductory screen while a self test is performed. Press the *PROCEED* soft key to go to the next screen (Figure 6).

NOTE: The date of the last valid calibration check will display as part of the spirometer's power-up sequence if a calibration check has not been performed in the current calendar day.

2. In the *"INITIAL SETUP"* screen the user is prompted to select certain configurable options. This screen will be displayed each time the spirometer is powered-up until the user sets the displayed options (Figure 7).
3. Using the cursor key, highlight each option and enter the desired settings using the keypad. Press the *DONE* soft key to go to the *"MAIN"* screen (Figure 5).

NOTE: For test accuracy, elevation must be entered.

4. From the "*MAIN"* screen, adjust the display appearance by pressing the *LIGHTER*, *DARKER*, and *BACKLIT* soft keys to the desired settings.

Spirometry Testing

Introduction to Spirometry Testing

The purpose of a spirometry test is to assess and monitor a patient's lung condition. The most common spirometry test is the Forced Vital Capacity (FVC) test. This test requires the subject to take a deep breath and then exhale into the spirometer as forcefully, rapidly and completely as possible. The FVC test results report how fast the air was exhaled (flow rate) and how much air was exhaled (volume). These parameters are compared to values derived from 'Predicted Normal Equations" based on the patient's age, height, gender and race. These equations are listed starting on page 60. Depending on the results, the healthcare professional will be able to determine whether the patient is normal, or has an obstructive or a restrictive lung pattern.

Obstructive diseases are characterized by an increased resistance to air flow. This resistance makes it more difficult to move air into and out of the lungs rapidly. An obstructive pattern is characterized by a reduction in the volume that can be exhaled in the first second of the FVC test (FEV1) and by a low FEV1/FVC ratio. The most common obstructive diseases are asthma, chronic bronchitis and emphysema. Asthma constricts the bronchial tubes but can be controlled by drug therapy. Bronchitis also constricts the bronchial tubes but may not respond to drug therapy. Emphysema is the slow, irreversible destruction of the alveoli, leading to collapsed airways.

Restrictive diseases impair the movement of the lungs or the volume of air that can be expelled by the lungs. They are characterized by a reduction in the total volume of air that can be exhaled. The FEV1/FVC ratio remains normal or increases. Gross obesity, lung fibrosis, neuromuscular diseases or paralysis can cause restrictive diseases. Several occupational related diseases such as "black lung" and "cotton dust lung" also result in a restrictive pattern.

In addition to the FVC test, the Renaissance II spirometer can perform Flow-Volume Loop (FVL), Slow Vital Capacity (SVC), Maximal Voluntary Ventilation (MVV), and FEV6 tests. These additional tests will sometimes provide more information that is helpful in the diagnosis of a patient's lung disorder.

Obtaining Good Test Results

Unlike many other medical tests in which the patient is passive, spirometry requires active cooperation and strenuous effort by the patient. Obtaining the subject's full understanding and cooperation is essential.

The 10 steps to good spirometry results are listed below:

- Patient should refrain from taking bronchodilators 6-8 hours prior to testing, unless instructed by a physician.
- Loosen any restrictive clothing. Remove loose dentures, candy, gum, etc.
- Ensure accurate input of ID#, height, weight, gender, birth date, and race.
- Patient may sit or stand, but be consistent and record position.

Warning

⚠ ***Patient fainting or falling due to dizziness may occur as a result of this test. Advise the patient to sit or stand comfortably near a chair during test.***

- The use of nose clips is optional but recommended.
- Explain procedure carefully and demonstrate how it is done.
- Coaching is critical. Remind patient to "BLAST" out the air - don't just blow! Keep going as long, as hard, and as completely as possible (at least 6 seconds).
- Watch the patient inhale maximally and exhale forcefully and completely with mouth and teeth firmly sealed around the mouthpiece. Watch and listen for the incentive display.
- If the test is unacceptable, identify the reason(s) and explain how to correct the technique.
- Obtain at least three acceptable and two reproducible tests. See pp. 1122 - 1123 of Reference 11 (page 91) for ATS acceptability and reproducibility criteria. If tests are below normal, consider administering a bronchodilator according to office protocol, then retest in 10 to 15 minutes, or as suggested by the physician.

As the test is performed, coaching messages or incentive messages, e.g.,“Start Test, Keep Going” appear on the display to encourage the patient. Depending on the user's preferences, a graph of the data or an animated incentive will be displayed during the test. These messages and graphics should be used to coach the subject to perform the test maximally.

Warning

⚠ ***This device should be used by trained healthcare professionals and is not intended for patient operation.***

Pre-Test Procedures

Calibration Verification

The American Thoracic Society (ATS) recommends that a three-speed calibration verification, using a calibrated syringe with a minimum volume of 3 liters, be performed on a daily basis to verify the accuracy of the system prior to testing patients. Puritan Bennett recommends using the 3-liter calibrated syringe specified in Table 1: *Basic Spirometry System and Accessories*, optional accessory item 12 (see page 9) for verifying the calibration of the Renaissance II. The syringe should be recertified for volume accuracy and leaks per manufacturer recommended intervals.

The Renaissance II can perform two types of calibration verifications: SSD and Cal Check.

The SSD calibration verification satisfies both ATS and Social Security Disability requirements for verification at three flow rates.

The Cal Check is performed at one flow rate and can be accessed immediately after the power-on self test, or from the Cal Check menu item (5) on the Main screen. When running a Cal Check, calibration syringes ranging in size from 1-liter to 8-liters may be used, and the Renaissance II will automatically determine the size of the syringe. A Cal Check may be desirable in addition to the daily three-speed (SSD) calibration to verify volume accuracy at multiple points during studies involving a large number of maneuvers.

SSD Calibration Verification

The Renaissance II's SSD calibration verification feature can be used to perform either the ATS recommended daily three-speed verification, or a verification suitable for Social Security Disability claims submissions. In both cases, the verifications are performed using a 3-L syringe at three flow rates: 3 L/sec, 1 L/sec, and 0.5L/sec.

To perform an ATS calibration verification, obtain a flow sensor and 3-L calibrated syringe, and follow the instructions starting on page 19. There is no need to enter any patient information prior to performing this verification. The date and time of the calibration verification will be retained in memory until the next time a calibration verification is performed.

Social Security Disability Testing requires that the calibration error at the tested flow rates is within ± 1% of the calibrating volume. In order for the spirometer to meet the ±1% requirement, a correction factor must be obtained to correct the measured volume. This correction factor is then applied to the measurements obtained during the patient tests. For this reason the sensor used to verify the spirometer's calibration for an SSD claims submission must also be used for the actual patient test.

NOTE: If the patient test will be submitted for Social Security Disability (SSD) determinations, enter patient information prior to performing the SSD calibration verification.

CAUTION:
Prior to verifying calibration, visually verify that there is no foreign material in the pressure tube and the tube is not damaged or kinked.

1. From the "*MAIN*" screen, press *2* on the keypad or scroll to *TEST* using the cursor key and press *ENTER* (Figure 8).
2. From the "*PRE MED TEST*" screen, press *3* on the keypad, or use the cursor key to scroll to *SSD CAL* and press *ENTER* (Figure 9).
3. On the "*SSD CAL*" screen, verify that the temperature and barometric pressure are correct. If not, scroll to the corresponding field and type the correct information using the numeric keypad *before* swiping the sensor. (Figure 10.)
4. Use the cursor key to scroll to the sensor code field and swipe the sensor (Figure 11) or enter the numeric code and press the *DONE* soft key.
5. Continue to follow the screen's directions when prompted.
6. Push the 3-Liter syringe plunger in smoothly over a period of approximately one-second for the 3 L/sec verification.
7. The dotted lines appearing on the display represent the upper and lower limits for the flow rate. While pushing the plunger in, the graph will develop on the display. Try to keep the graph within the dotted lines. The "*SSD CAL*" screen will prompt faster/slower if necessary, (Figure 12). Repeat until you are prompted to proceed.
8. Press the *YES* soft key to proceed with the 1 L/sec verification, and follow the same procedures as before (steps 6 through 7) when prompted on the screen for the next calibration maneuver. Push the 3-Liter syringe plunger in over a period of approximately 3 seconds for the 1 L/sec verification.
9. Press the *YES* soft key to proceed with the 0.5L/sec verification.

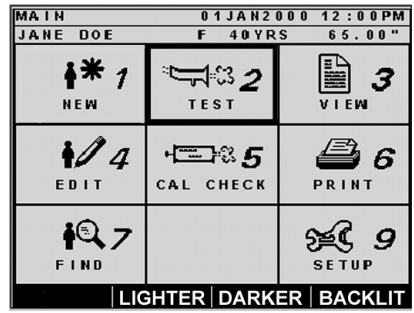


Figure 8: Select TEST from MAIN screen

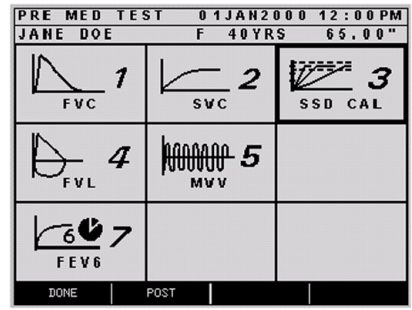


Figure 9: Select SSD CAL from PRE-MED TEST screen

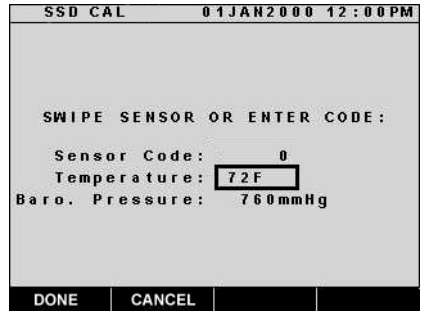


Figure 10: Enter room temperature and barometric pressure

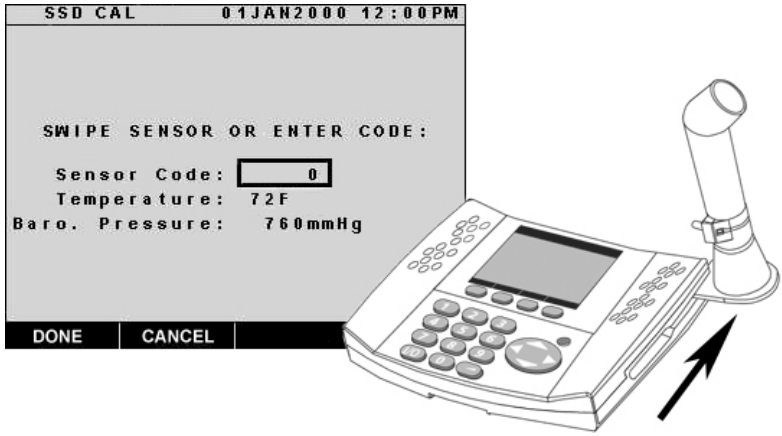


Figure 11: Swipe the sensor

10. Follow the directions on the screen and push the 3-Liter syringe plunger in over a period of approximately 6 seconds for the last SSD verification.
11. The final "*SSD CAL*" screen (Figure 13) will display the volume of the calibration syringe, the corrected measured volume and associated percentage error for each of the three flow rates indicated on the illustration.
12. Press *DONE* to save the calibration results, *DISCARD* to delete, or *PRINT* to print out a record of the results. See *Printing Results* on page 38 for more information on printing.

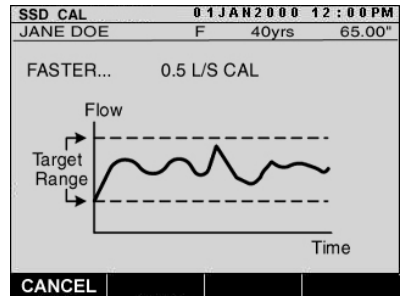


Figure 12: SSD CAL

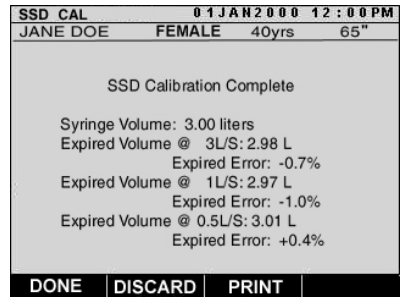


Figure 13: SSD CAL Complete

NOTE: When performing either the CAL check or SSD CAL maneuver, if the measured flow or volume is not within allowable range, the screen will indicate "Unsuccessful CAL Try Again?" Refer to the Calibration Error section of the Troubleshooting Guide on page 52 to resolve the problem.

NOTE: Verify that the temperature of the room is the same as the temperature noted for the calibration test. For every degree discrepancy, there will be a corresponding 0.15% error in the test results.

NOTE: Verify that the displayed barometric pressure is correct. If not correct, there will be an error in the inspired volume (FIVC) during an FVL maneuver of approximately -1.3% for every 1,000 feet above sea level. Refer to the System Configuration section starting on page 78 for more information. The barometric pressure displayed is based on the initial elevation setting of the spirometer. However, the barometric pressure may be changed and the spirometer will, from that point on, use the new value entered.

Cal Check

CAUTION:
Prior to verifying calibration, visually verify that there is no foreign material in the pressure tube and the tube is not damaged or kinked.

1. Connect the pressure tube to the spirometer and to the FSII sensor. (Shown previously in Figures 3 and 4.)
2. Following the power-up and initial setup screens, the "*CAL NOW?*" screen will appear on the display.
3. Press the *YES* soft key to perform the calibration check or *NO* to proceed with a test. When prompted, swipe the sensor or enter the numeric code printed on the sensor (Figure 14).

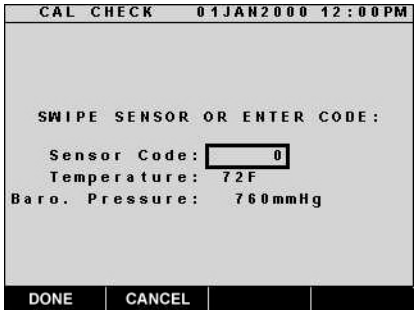


Figure 14: Enter code or swipe sensor

NOTE: You may also perform a Cal Check by pressing ***5*** on the keypad at the "***MAIN***" screen or scrolling to ***CAL CHECK*** with the cursor key and pressing ***ENTER***.

4. Continue to follow the screen's directions when prompted (Figure 15).
5. When the display prompts, push the plunger in smoothly and completely over approximately one to two seconds.
6. Press the *DONE* soft key if complete, or pull the plunger out to complete an INSPIRATORY CAL check. (Figure 16.)
7. If the calibration check was successful, the syringe volume, measured volume and error percentage will be displayed on the final screen. (Figure 17.)
8. To assure accurate patient testing, the calibration check volume error is required to be ±3% or less. If the error is greater than ±3%, refer to the Calibration Error section of the Troubleshooting Guide on page 52 of this User's Manual.
9. Press *DONE* to save the Cal Check, *DISCARD* to delete, or *PRINT* to print out a record of the Cal Check results. See *Printing Results* on page 38 for more information on printing.

NOTES:

- The ATS does not require an Inspiratory Calibration.
- The Renaissance II's Inspiratory Calibration function has been validated only for elevations below 4000 feet.

Figure 15: Attaching syringe

Figure 16: Calibration check

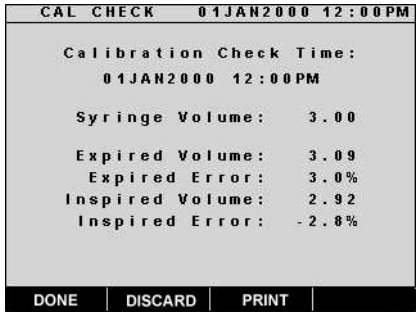


Figure 17: Cal Check complete

Patient Preparation

Coaching the patient will result in more accurate results. There are several possible reasons why accurate results are not obtained the first time.

- Not taking a maximal inhalation at the beginning of the maneuver.
- Not blasting the air out quickly or starting slow.
- Not blowing out completely.

WARNING

- ***Physicians should assess patient's ability to perform spirometry testing prior to administering the test.***
- ***Patient fainting or falling due to dizziness may occur as a result of this test. Advise the patient to sit or stand comfortably near a chair during test.***
- ***User should visually inspect the FSII sensor for loose particles/ foreign material prior to patient use.***

NOTES:

- Demonstrating the test using your own FSII sensor is strongly recommended for patients who have never performed a spirometry test before.
- The American Thoracic Society (ATS) recommends performing a three-speed calibration check on a daily basis.
- Materials used to make this Renaissance II Spirometry System and accessories contain no Latex.

Verify that the opening of the sensor is not blocked.

Instruct the patient to:

- Relax
- Loosen tight clothing, such as neckties or tight collars
- Remove dentures, candy, gum, etc.
- Elevate chin and extend the neck slightly
- Avoid leaning forward
- Use a nose clip if available *(strongly recommended)*
- Blast out air forcefully, completely, and as long as possible

WARNING

- ***Results from spirometry testing should not be the sole source for determining a patient's diagnosis and treatment. Other clinical data, such as patient symptoms and respiratory history, should always be considered.***
- ***Predicted values will be extrapolated for patients with age or height outside the age and/or height limits supported by the selected author's normal equations.***

NOTES:

- Verify that the temperature of the room is the same as the temperature noted for the calibration test. For every degree discrepancy, there will be a corresponding 0.15% error in the test results.
- Verify that the displayed barometric pressure is correct. If not correct, there will be an error in the inspired volume (FIVC) during an FVL maneuver of approximately -1.3% for every 1,000 feet above sea level. Refer to the System Configuration section starting on page 78 for more information. The barometric pressure displayed is based on the initial elevation setting of the spirometer. However, the barometric pressure may be changed and the spirometer will, from that point on, use the new value entered.

Entering New Patient Data

1. From the "*MAIN*" screen press *1* on the keypad or use the cursor key to scroll to the *NEW* option and press *ENTER*.
2. When prompted to start a new patient, press the *YES* soft key. Pressing *NO* will return you to the "*MAIN*" screen.
3. Enter data on the "*NEW PATIENT*" screen by using alpha or numeric characters when appropriate. Press *ENTER* after each field is completed. Numbers may be entered directly using the numeric keys with the spirometer in numeric mode. Alpha characters can only be entered with the spirometer in alpha mode.

NOTE: When in numeric mode (Figure 18), only numbers may be typed on the key pad. Pressing the ***ABC...*** soft key puts the key pad into alpha character mode (Figure 19) allowing both letters and numbers to be entered from the key pad.

Alpha character entry is modeled after cell phones. For example, the first key press displays the first letter, the second press displays the second letter, and so on until the last key press displays the numeral. A pause in pressing the key causes the entry point to move to the next character.

4. When the desired character is highlighted, pause or press the cursor key to move to the next character space.
5. When the current field is complete, press the *ENTER* key to move to the next field and repeat the process. You must enter the patient's height, birth date, and gender or no interpretation or predicted values will be displayed.
6. Enter the patient's race, by pressing the corresponding number on the keypad and then pressing *ENTER*.

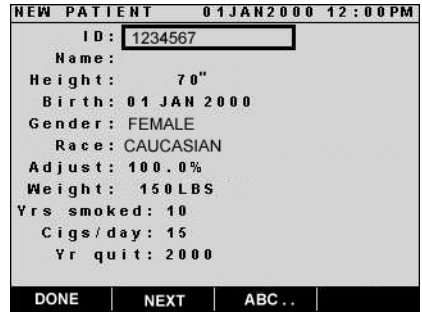


Figure 18: New Patient (Numeric)

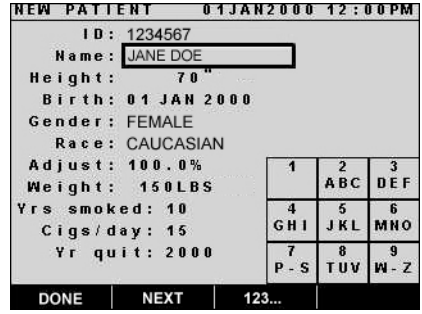


Figure 19: New Patient (Alpha)

7. If desired, apply an adjustment factor to which the predicted value and LLN calculations will be multiplied. Table 2 lists the factory default settings and the range of adjustment. See the article *Spirometric Reference Values from a Sample of the General U. S. Population*[16] for more information on race adjustment.

Table 2: Race Adjustment Settings

*Factory Default Setting**	*Adjustment Range*
African American 88% Asian 100% Caucasian 100% Hispanic 100% Other 100%	10% - 110%
* If a race adjustment setting other than the factory default has been entered, the spirometer retains the new setting in memory. Ensure the race adjustment setting is correct for each new patient.	

NOTE: When Caucasian race is selected, adjustment settings other than 100% are ignored in predicted value and LLN calculations.

8. Continue entering the patient's weight, and smoking history (years smoked, cigarettes per day, and year quit), if applicable. The allowable weight range is 30 - 440 lb. (15 - 200 kg.). See the section, Lung Age Interpretation, on page 47 for information regarding the applicability of smoking history.
9. Press the *NEXT* soft key to enter comments and physician, technician, medication, and dosage information. If you need to change any information on the previous screen press the *BACK* soft key.
10. When all desired information is entered, press the *DONE* soft key to save the data and return to the "*MAIN*" screen.

Pre-Med Testing Procedures

FVC (Forced Vital Capacity) Test Procedure

WARNING

Patient fainting or falling due to dizziness may occur as a result of this test. Advise the patient to sit or stand comfortably near a chair during test.

1. From the "*MAIN*" screen, press *2* on the keypad or scroll to *TEST* using the cursor key and press *ENTER*.
2. From the "*PRE MED TEST*" screen, press *1* on the keypad or use the cursor key to scroll to *FVC* and press *ENTER*.
3. When prompted, swipe the sensor or type the six-digit numeric code and press *ENTER*.
4. Enter the room temperature and barometric pressure, if necessary, and press the *DONE* soft key. The sensor will zero and the spirometer will display the "*FVC TEST*" screen and START TEST prompt (Figure 20).

Instruct the patient to:

- Place the sensor in his/her mouth.
- Close lips and teeth around the sensor in such a way that a tight seal is formed.

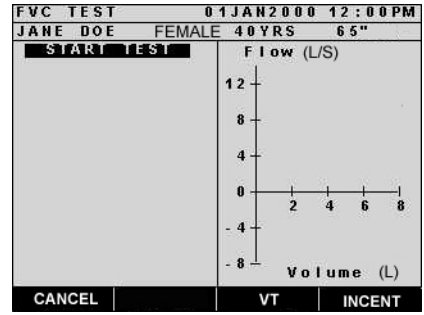


Figure 20: FVC Test

Coach the patient enthusiastically.

"Take a good, deep breath. Pull, pull it all in. Now BLAST out Keep blowing, harder..... That's good! Squeeze it out, squeeze it all out.....Good job!"

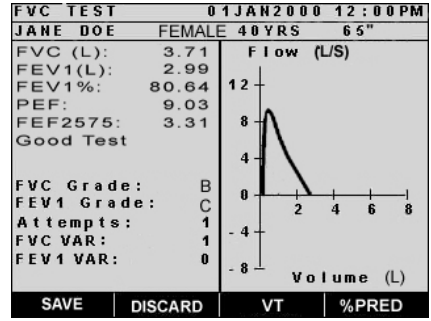


Figure 21: FVC Test Complete

5. The spirometer will display an incentive message, such as "Keep Going" or "All the Way" and the elapsed time of the test, while the real-time curve is being drawn. The patient should keep blowing until the TEST COMPLETE message appears. To display an incentive bar graph instead of the real-time curve, press the *INCENT* soft key when the START TEST prompt appears.
6. Upon completion of the test, the spirometer will display the flow-volume curve, measured values, acceptability messages, quality grades, number of maneuvers performed, and FVC and FEV1 variability depending on the options enabled during system configuration (Figure 21). To view the volume-time curve, press the *VT* soft key. To view the results as a percentage of the predicted values, press the *%PRED* soft key.
7. Press the *SAVE* soft key if the maneuver is acceptable. Press the *DISCARD* soft key if the maneuver is unacceptable. The display returns to the "*PRE-MED TEST*" screen.
8. Select *FVC* again and repeat the above process up to eight times, until at least three acceptable and two reproducible maneuvers have been obtained.

NOTE: The value for FEV6 can only be obtained by administering an FEV6 test.

SVC (Slow Vital Capacity) Test Procedure

WARNING

⚠ ***Patient fainting or falling due to dizziness may occur as a result of this test. Advise the patient to sit or stand comfortably near a chair during test.***

1. From the "*MAIN*" screen, press *2* on the keypad or scroll to *TEST* using the cursor key and press *ENTER*.
2. From the "*PRE MED TEST*" screen press *2* on the keypad or use the cursor key to scroll to *SVC* and press *ENTER*.
3. When prompted, swipe the sensor or type the numeric code and press *ENTER*.
4. Enter the room temperature and barometric pressure, if necessary, and press the *DONE* soft key. The sensor will zero and the spirometer will display the "*SVC TEST*" screen and START TEST prompt.

Instruct the patient to:

- Place the sensor in his/her mouth.
- Close lips and teeth around the sensor in such a way that a tight seal is formed.

Coach the patient enthusiastically.

"Take a good, deep breath. Pull, pull it all in. Now exhale normally. That's good! Squeeze it out, squeeze it all out. Good job!"

5. The spirometer will display an incentive message and the elapsed time of the test while the real-time curve is drawn. To display an incentive bar graph instead of the real-time curve, press the *INCENT* soft key when the START TEST prompt appears.
6. Upon completion of the test maneuver the spirometer will display the volume-time curve, measured, predicted, and % of predicted values, and number of maneuvers performed (Figure 22).

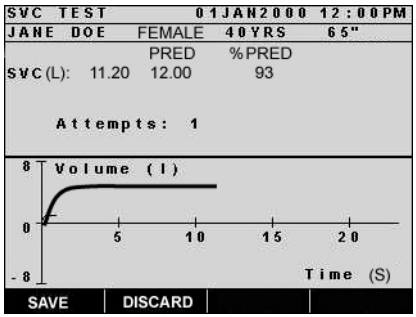


Figure 22: SVC Test Complete

7. Press the *SAVE* soft key if the maneuver is acceptable. Press the *DISCARD* soft key if the maneuver is unacceptable. The display returns to the "*PRE-MED TEST*" screen. Repeat the test up to 8 times, if necessary.

FVL (Flow Volume Loop) Test Procedure

WARNING

⚠ ***Patient fainting or falling due to dizziness may occur as a result of this test. Advise the patient to sit or stand comfortably near a chair during test.***

1. From the "*MAIN*" screen, press *2* on the keypad or scroll to *TEST* using the cursor key and press *ENTER*.
2. From the "*PRE MED TEST*" screen, press *4* on the keypad or use the cursor key to scroll to *FVL* and press *ENTER*.
3. When prompted, swipe the sensor or type the numeric code and press *ENTER*.
4. Enter the room temperature and barometric pressure, if necessary, and press the *DONE* soft key. The sensor will zero and the spirometer will display the "*FVL TEST*" screen and START TEST prompt.

NOTES:

- Verify that the temperature of the room is the same as the temperature noted for the calibration test. For every degree discrepancy, there will be a corresponding 0.15% error in the test results.
- Verify that the displayed barometric pressure is correct. If not correct, there will be an error in the inspired volume (FIVC) of approximately (-1.3%) for every 1,000 feet above sea level. Refer to the System Configuration section starting on page 78 for more information. The barometric pressure displayed is based on the initial elevation setting of the spirometer. However, the barometric pressure may be changed and the spirometer will continue to use the value entered.
- If you choose to obtain barometric pressure from an agency, such as the weather service, verify that the value is NOT corrected to sea level.

Instruct the patient to:

- Place the sensor in his/her mouth
- Close lips and teeth around the sensor in such a way that a tight seal is formed.

Coach the patient enthusiastically.

"Take a good, deep breath. Pull, pull it all in. Now BLAST out. Keep blowing, harder. That's good! Squeeze it out, and suck it back in, deep, deep. Good job!"

5. When the spirometer detects that the expiratory portion of the maneuver is complete, the incentive message will change to "Deep Breath In!"
6. Instruct the patient to inhale as quickly, and fully as possible.
7. The spirometer will continue to display an incentive message and the elapsed time of the test while the real-time curve is drawn. To display an incentive bar graph instead of the real-time curve, press the *INCENT* soft key when the START TEST prompt appears.
8. Upon completion of the test maneuver the spirometer will display the flow-volume curve, measured values, quality message, quality grades, number of maneuvers performed, and FVC and FEV1 variability (Figure 23). To view the volume-time curve press the *VT* soft key. To view the results as a percentage of the predicted values, press the *%PRED* soft key.

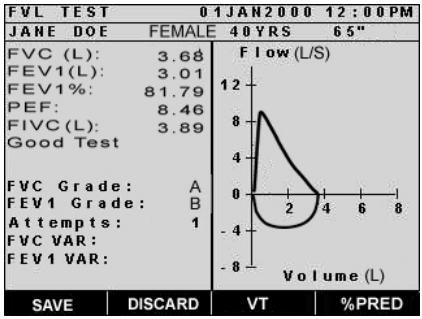


Figure 23: FVL Test Complete

9. Press the *SAVE* soft key if the maneuver is acceptable. Press the *DISCARD* soft key if the maneuver is unacceptable. The display returns to the "*PRE-MED TEST*" Screen.
10. Select *FVL* again and repeat the above process up to eight times until at least three acceptable and two reproducible maneuvers have been obtained.

MVV (Maximal Voluntary Ventilation) Test Procedure

WARNING

Patient fainting or falling due to dizziness may occur as a result of this test. Advise the patient to sit or stand comfortably near a chair during test.

1. From the "*MAIN*" screen, press *2* on the keypad or scroll to *TEST* using the cursor key and press *ENTER*.
2. From the "*PRE MED TEST*" screen press *5* on the keypad or use the cursor key to scroll to *MVV* and press *ENTER*.
3. When prompted, swipe the sensor or type the numeric code and press *ENTER*.
4. Enter the room temperature and barometric pressure if necessary and press the *DONE* soft key. The sensor will zero and the spirometer will display the "*MVV TEST*" screen and START TEST prompt.

Instruct the patient to:

- Place the sensor in his/her mouth.
- Close lips and teeth around the sensor in such a way that a tight seal is formed.

Coach the patient enthusiastically.

"Take a good, deep breath. Pull, pull it all in." "Now breathe out and in deeply and quickly." "Keep going... that's good!" "Keep going! Good job!"

5. The spirometer will display an incentive message and the elapsed time of the test while the real-time curve is drawn. To display an incentive bar graph instead of the real-time curve, press the *INCENT* soft key when the START TEST prompt appears.
6. Upon completion of the test maneuver, the spirometer will display the volume-time curve, measured, predicted, and % of predicted values, and number of maneuvers performed (Figure 24).
7. Press the *SAVE* soft key if the maneuver is acceptable. Press the *DISCARD* soft key if the maneuver is unacceptable. The display returns to the "*PRE-MED TEST*" screen. Repeat the test if necessary.

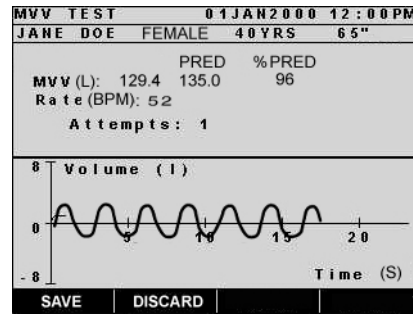


Figure 24: MVV Test Complete

FEV6 (Forced Expiratory Volume in 6 sec.) Test Procedure

WARNING

Patient fainting or falling due to dizziness may occur as a result of this test. Advise the patient to sit or stand comfortably near a chair during test.

1. From the "*MAIN*" screen, press *2* on the keypad or scroll to *TEST* using the cursor key and press *ENTER*.
2. From the "*PRE MED TEST*" screen press *7* on the keypad or use the cursor key to scroll to *FEV6* and press *ENTER*.
3. When prompted, swipe the sensor or type the numeric code and press *ENTER*.
4. Enter the room temperature and barometric pressure, if necessary, and press the *DONE* soft key. The sensor will zero and the spirometer will display the "*FEV6 TEST*" screen and START TEST prompt.

Instruct the patient to:

- Place the sensor in his/her mouth.
- Close lips and teeth around the sensor in such a way that a tight seal is formed.

Coach the patient enthusiastically.

"Take a good, deep breath. Pull, pull it all in. Now BLAST out. Keep blowing, harder. That's good! Squeeze it out, squeeze it all out. Good job!"

5. The spirometer will display an incentive message and the elapsed time of the test while the real-time curve is drawn. To display an incentive bar graph instead of the real-time curve, press the *INCENT* soft key when the Start Test prompt appears.
6. The FEV6 test will automatically terminate after six seconds. At this time, the spirometer displays the flow-volume curve, measured values, acceptability messages, quality grades, number of maneuvers performed, and FEV6 and FEV1 variability (Figure 25). To view the volume-time curve, press the *VT*

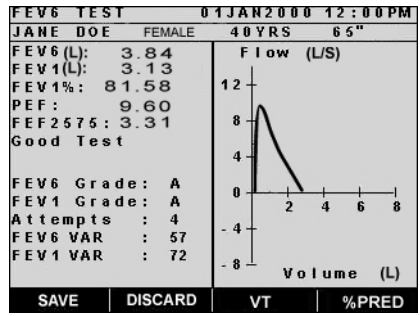


Figure 25: FEV6 Test Complete

soft key. To view the results as a percentage of the predicted values press the *%PRED* soft key.

7. Press the *SAVE* soft key if the maneuver is acceptable. Press the *DISCARD* soft key if the maneuver is unacceptable. The display returns to the "*PRE-MED TEST*" screen.
8. Select *FEV6* again and repeat the above process up to eight times until at least three acceptable and two reproducible maneuvers have been obtained.

NOTE: The value for FEV6 can only be obtained by administering an FEV6 test.

Post-Med Testing Procedures

After completing the pre-medication (baseline) testing, administering the medication (usually an inhaled bronchodilator), and switching the spirometer to Post-Med test mode, the post-medication testing may begin.

The patient's session must be retrieved from memory if Post-Med testing is performed on a patient whose Pre-Med test was performed more than 30 minutes prior (if spirometer has powered off), or if Pre-Med testing is performed on any patient other than the current one.

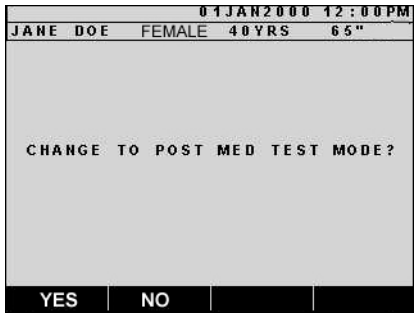


Figure 26: Change to Post-Med Test Mode

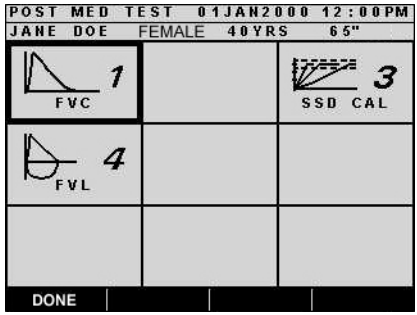


Figure 27: Post Med Test Screen

NOTES:

- The LCD panel will turn off after 5 minutes (and the unit will power off after 30 minutes) with no user input. To bring back the display before the 30-minute limit, press any key.
- After 4 hours, a Post-Med test is not allowed and the soft key is not available.

To retrieve a patient's session from memory:

1. From the "*MAIN*" screen, press *7* or scroll to *FIND* using the cursor key.
2. Type the patient's name or ID number (depending upon the spirometer's Display configuration) in the FIND PATIENT field or press the *SCROLL* soft key and use the cursor arrow to select the patient's name or ID number. (See *System Configuration* on page 78 and *Display (5)* on page 83 for information on how to configure the unit to show patients by name or ID.)
3. Press the following soft keys in order: *MARK* > *CURRENT* > *BACK* > *RECALL*. The spirometer is now ready to switch to Post-Med test mode.

To switch to Post-Med test mode and perform Post-Med testing:

1. From the "*PRE MED TEST*" screen press the *POST* soft key. The "*CHANGE TO POST-MED TEST MODE?*" message (Figure 26) appears.
2. Press the *YES* soft key. The display heading changes to *"POST MED TEST"* (Figure 27), and the test options appear just as they did for the "*PRE MED TEST*" screen. The only test options appearing on the "*POST MED TEST"* screen are those previously performed in Pre-Med testing.
3. Proceed as described in the Pre-Med testing section of this User's Manual for each test.

Post-Test Procedures

Saving Results

The Renaissance II spirometer saves all patient data and test data, provided the *SAVE* soft key is pressed after each maneuver.

NOTES:

- If a maneuver is saved, it is retained in memory until the entire patient session is deleted. This includes abnormally large maneuvers that occur as a result of an occluded flow sensor and that subsequently may be labeled as the best maneuver.
- The spirometer will store multiple tests for each maneuver, but will only display and print up to the best three Pre-Med and Post-Med FVC/FVL and FEV6 maneuvers, the single best Pre-Med and Post-Med SVC and MVV maneuvers, and the last maneuver performed.
- If the user does not press the ***POST*** soft key prior to performing Post-Med tests, the maneuvers will be stored as Pre-Med tests and cannot be transferred to Post-Med status.

Viewing Results

The patient whose test results are currently in memory may be viewed in several formats.

1. From the "*MAIN*" screen press *3* on the keypad, or scroll to the *VIEW* option and press *ENTER*.
2. The "*SELECT VIEW*" screen appears, indicating the view options as shown in Figure 28. See Table 3 for the definitions of each option.

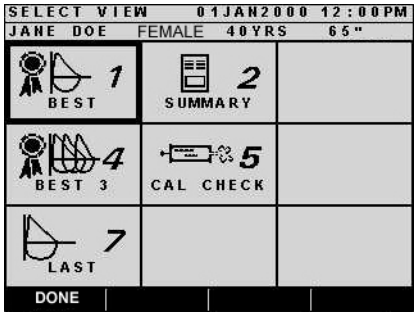
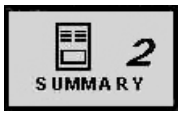


Figure 28: Select View screen

Table 3: View Options

	Displays results for the single best Pre-Med or Post-Med effort as determined by the "Best Criteria" configured in Spirometry Options.*
	Summarizes each Pre-Med or Post-Med maneuver with number of attempts, number of acceptable tests, number of reproducible tests, and interpretation if these options are enabled in Spirometry Options.*
	Displays test results for the best three Pre-Med or Post-Med efforts as determined by the "Best Criteria" configured in Spirometry Options.*
	Displays last calibration check results.
LAST 	Displays test results for the most recent maneuver only.

*See System Configuration and Spirometry Options (1) on page 78 for information on configuring the spirometer.

After selecting the desired view option, several soft key options are available:

- Pressing the *NEXT* soft key scrolls the display of numerical test data.
- Pressing the *CURVE* soft key will display the flow-volume curve(s) for displayed FVC/FVL or FEV6 test data.
- Pressing the *VT* soft key while the flow-volume curves are displayed, shows the associated volume-time curve.
- Pressing the *FV* soft key while the volume-time curves are displayed shows the flow-volume graph.
- Pressing the *DATA* soft key returns to the numerical test data display.
- Pressing the *POST* soft key will change the display to the Post-medication test results for the view option chosen.

Printing Results

The Renaissance II Spirometry System operates with selected Hewlett-Packard, Epson, and Canon printers (see *Print Options (3)* on page 80 for supported printers). The spirometer's configuration settings may be changed to match the printer. Refer to *System Configuration* on page 78, for information on changing the spirometer's configuration.

To print a report:

1. Switch to the "*SELECT REPORT*" screen (Figure 29) by pressing *6* from the "*MAIN*" screen or using the cursor key to scroll to *PRINT* and pressing *ENTER*. Table 4 lists the available reports and their descriptions.
2. Connect a compatible printer to the parallel port on the base station using the printer cable (see Table 1, item 16). The printer should be turned off when connecting the cable.

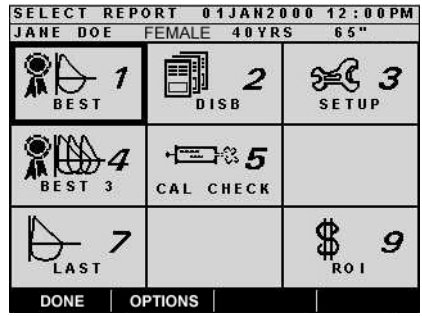


Figure 29: Select Report screen

3. Turn the printer on and verify that it is online and ready to print.
4. Dock the Renaissance II spirometer onto the base station. The spirometer must stay docked in the base station for the duration of printing. If you wish to alter the format of the printed report, press the *OPTIONS* soft key and change the information. Press the *DONE* soft key to return to the "*SELECT REPORT*" screen.
5. Press the appropriate number on the keypad or scroll to the desired report and press *ENTER* to send the report to the printer.

Table 4: Report Selections

	Prints the results for the single best Pre-Med and Post-Med effort for each type of maneuver as defined by the "Best Criteria" configured in Spirometry Options.*
	Prints a report suitable for Social Security Disability claims submissions.
	Prints the spirometer configuration settings.
	Prints test results for the best three Pre-Med and Post-Med FVC/FVL and FEV6 maneuvers and the single best Pre-Med and Post-Med SVC and MVV maneuvers as defined by the "Best Criteria" configured in Spirometry Options.*
	Prints the results of the last calibration check.
	Prints the test results for the most recent maneuver.
	Displays or prints a Return On Investment report.

*See System Configuration and Spirometry Options (1) on page 78 for information on configuring the spirometer.

The Return on Investment (ROI) Report can be used as a cost management tool for calculating and displaying Total Income, Total Cost, Net Income, ROI, and Payback (in months) based upon the following values supplied by the user:

- Purchase price
- Covered tests per week
- Cost per covered test
- Reimbursement (per test)

The Renaissance II calculates ROI and Payback in the following manner:

ROI = (Reimbursement / Cost per covered test) x 100%
Payback (months) = Purchase price / Net income (monthly)

NOTE: The existence of coding does not guarantee coverage or payment for any procedure by any payer. In any case, reimbursement is only available for medically necessary procedures (in accordance with specific payer guidelines.)

To print an ROI report:

1. From the *SELECT REPORT* screen, press *9* or scroll to *ROI* and press *ENTER*.
2. Type the purchase price and press *ENTER*.
3. Type the number of tests performed per week and press *ENTER*.
4. Type the cost per test and press *ENTER*.
5. Type the amount reimbursed per test. The ROI is displayed on the screen.
6. Press the *PRINT* soft key to print the ROI report or the *DONE* soft key to return to the "*SELECT REPORT*" screen without printing.

Printing Reports for Multiple Patients

The Renaissance II spirometer allows printing reports for multiple patients at the same time.

To print multiple reports:

1. Prepare the printer and spirometer system as described above. The spirometer must stay docked in the base station for the duration of printing.
2. From the "*MAIN*" screen, press *7* on the keypad or scroll to *FIND* with the cursor arrow key and press *ENTER*.
3. Press the *SCROLL* soft key.
4. Use the cursor arrow key to highlight the patient whose record you want to print. To print all patient records, highlight any patient.
5. Press the *MARK* soft key.
6. Press the *CURRENT* soft key to select the record. Continue with the cursor arrow key and *CURRENT* soft key to highlight and select the patient records you want to print. To select all patient records, press the *ALL* soft key. To select all records that have been added or changed since last

printed or downloaded to a PC, press the *NEW* soft key. When you have finished selecting records, press the *BACK* soft key.

7. Press the *NEXT*, then *PRINT* soft keys. The best Pre-Med and Post-Med result for each maneuver performed in a patient's session is printed.

Deleting Patient Data

The Renaissance II spirometer can store data for up to 1000 patients. When the memory becomes full or if the unit is sent in for repair or exchange, it may become necessary to erase patient data.

NOTE: In order to comply with HIPAA, the user should consider deleting all patient data prior to sending the unit to Puritan Bennett.

To delete patient data:

1. From the "*MAIN*" screen, press *7* on the keypad or use the cursor arrow key to scroll to *FIND* and press *ENTER*.
2. Press the *SCROLL* soft key.
3. Use the cursor arrow key to highlight the patient to be deleted. If you want to delete all patient data, highlight any patient.
4. Press the *MARK* soft key.
5. Use the *CURRENT* or *ALL* soft keys to delete either the highlighted patient or all patient data.
6. Press the *BACK* soft key.
7. Press the *NEXT* soft key.
8. Press the *DELETE* soft key. A confirmation screen appears if this option has been enabled (see *System Configuration* on page 78 and *Storage (8)* on page 83 for information on changing the spirometer's configuration and enabling the Confirm Before Delete option).
9. Press the *YES* soft key to delete.

The selected patient data is deleted. If a failure has occurred that does not allow you to access the main screen, the memory cannot be deleted.

The optional *DataFlow*™ Data Management Software (Table 1, optional accessory item 15, on page 9) allows the user to upload patient data to a PC for archival in a database. Performing this operation prior to deleting patient data from the Renaissance II Spirometer provides a solution for long-term patient data storage. See the section, *Using the Renaissance II with a PC and Dataflow™ Software*, on page 77 for more information.

Interpretation of the Results

Acceptability and Reproducibility

Achieving high quality test results depends upon patient effort and technician coaching. The Renaissance II spirometer determines the quality of each patient effort by measuring the acceptability and reproducibility of the maneuver and displaying an "Acceptability Message" that will help both you and your patient achieve accurate results.

The Renaissance II determines the acceptability and reproducibility of maneuvers based upon the ATS acceptability and reproducibility criteria[11]. These criteria are used to determine which message from Table 5 is displayed at the end of a maneuver.

A test is considered acceptable if the "Good Test" message is displayed at the end of the maneuver. If a different message is displayed, use the associated coaching instruction in Table 5 to try to improve the patient's test outcome.

The Renaissance II measures reproducibility (also called variability) after at least two repetitions of a particular maneuver have been performed, and displays the measurements on the screen and in printed reports as FVC VAR and FEV1 VAR. Results are considered reproducible if the two largest FVC and FEV1 measurements are within 200 ml of each other.

According to the ATS, testing may be concluded when at least 3 acceptable and 2 reproducible spirograms have been obtained, or when a total of eight tests have been performed, or the patient cannot or should not continue.

To view the number of acceptable and reproducible tests:

1. Make sure the spirometer is configured so that acceptability and reproducibility options are enabled (see the *System Configuration* section starting on page 78, to configure Spirometry Options).
2. From the "*MAIN*" screen, press *3* on the keypad or scroll to *VIEW* with the cursor arrow key and press *ENTER*. The "*SELECT VIEW*" screen appears.
3. From the "*SELECT VIEW*" screen, press *2* or scroll to *SUMMARY* with the cursor arrow key and press *ENTER*. The number of acceptable and reproducible tests is shown in the display.

If "Accept Msgs" is enabled in the Print Options screen, the Acceptability Message will print on the test page if the *LAST* test is selected for printing (see the *System Configuration* section starting on page 78, to configure Spirometry and Print Options, and *Printing Results* on page 38 for information regarding printing reports).

Table 5: Test Acceptability Messages

Message	Definition	Coaching Instruction
START FASTER	Extrapolated volume is greater than 5% of FVC or greater than 150 ml (5% if FVC $\geq$ 3 liters; 150 ml if FVC < 3 liters).	Patient must not hesitate or leak out any air at the beginning of the test.
AVOID COUGHING	Substantial (> 50%) drop and recovery in flow within the first second.	Ask the patient to clear his/her throat and/or offer a drink of water.
BLOW OUT LONGER	FET < 6 seconds for FVC maneuvers or FET < 6 seconds and exhaled volume in last 0.5 second of test > 100 ml for FEV6 maneuvers.	Coach the patient to blow out longer.
BLOW OUT MORE	Flow > 200 ml/s during last 100 ms before first occurrence of peak volume or < 2 s plateau (time from end of test to first occurrence of peak volume –20 ml).	The patient quit before his/her lungs were completely empty. Coach the patient to keep blowing as long as possible.
BLOW OUT HARDER	Time to PEF > 120 ms (for FEV6 maneuvers only).	Instruct the patient to blast out air forcefully.
FVC VARIABLE	There is a difference of at least 200 ml between the two best FVC values. The difference must be less than 200 ml.	Observe patient performance for differences between good tests and those with high variability and instruct accordingly.
FEV1 VARIABLE	There is a difference of at least 200 ml between the two best FEV1 values. The difference must be less than 200 ml.	Observe patient performance for differences between good tests and those with high variability and instruct accordingly.
PEF VARIABLE	There is a difference of at least 10% and 1 L/sec between the last and best PEF values.	Observe patient performance for differences between good tests and those with high variability and instruct accordingly.
FVC GREATER THAN FIVC	FIVC < 90% FVC. Exhalation significantly greater than inhalation.	Instruct the patient to inhale completely at the end of the test.
FIVC GREATER THAN FVC	FVC < 90% FIVC. Inhalation significantly greater than exhalation.	Instruct the patient to blow out more completely.
GOOD TEST!	No problems detected.	N/A

Grading Criteria

Unlike many other medical tests in which the patient is passive, spirometry requires active cooperation and strenuous effort by the patient. The ability of clinicians to elicit this effort varies widely, but can be improved with experience and feedback.

The Quality Grades, which range from A to F, are displayed on screen and printed on the Best and Best 3 reports for the FVC/FEV1 and FEV6/FEV1 tests if the QC Grades option is enabled. The Quality Grades are an indication of the reliability of each of these measurements, and physicians may use them to judge their degree of confidence in the results. The grades are also an indicator of the short-term reproducibility of the FVC/FEV1, and FEV6/FEV1 measurements for that patient.

The Renaissance II assigns a Quality Grade according to the criteria shown in Tables 6 and 7. Use the grade in conjunction with the Acceptability Messages and coaching instructions in Table 5 to improve patient test performance.

NOTE: It is possible to have a "Good Test" Acceptability Message accompanied by a low QC grade. ***If the first FVC or FEV6 maneuver is acceptable, the Quality Grade will be D by definition (see Tables 6 and 7).*** It is not until there are at least 2 acceptable maneuvers that there is the possibility for a higher QC grade.

Table 6: Quality Grades for FVC/FEV1 Tests

A	At least 3 acceptable maneuvers with reproducibility of < 120 ml. Exceeds ATS acceptability and reproducibility criteria.
B	At least 3 acceptable maneuvers with reproducibility of ≤ 200 ml. Meets ATS acceptability and reproducibility criteria.
C	At least 2 acceptable maneuvers with reproducibility of ≤ 280 ml. Slightly below ATS acceptability and reproducibility criteria.
D	At least 1 acceptable maneuver with reproducibility of ≤ 360 ml. Substantially below ATS acceptability and reproducibility criteria.
F	No acceptable maneuvers or reproducibility of > 360 ml. All other cases.

Table 7: Quality Grades for FEV6/FEV1 Tests

A	At least 2 acceptable maneuvers with reproducibility of ≤ 100 ml.
B	At least 2 acceptable maneuvers with reproducibility of ≤ 150 ml.
C	At least 2 acceptable maneuvers with reproducibility of ≤ 200 ml.
D	At least 2 acceptable maneuvers with reproducibility of ≤ 200 ml OR at least 1 acceptable maneuver.
F	No acceptable maneuvers.

To ensure that the Quality Grades are displayed and printed in reports, enable the QC Grades option in the Spirometry Options screen of the Setup menu (see *System Configuration* and *Spirometry Options (1)* starting on page 78 for information on configuring the spirometer).

Interpretation Criteria

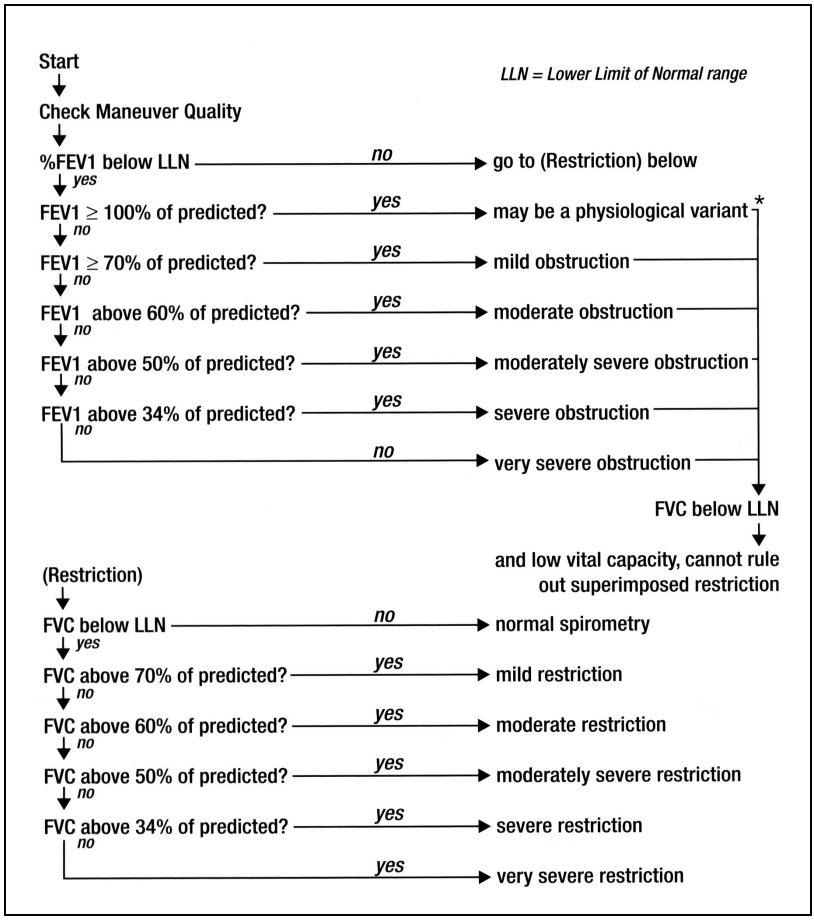
Upon completion of an FVC or FEV6 test session, the Renaissance II spirometer will generate an interpretation of the test data. The interpretation criteria are those suggested by the American Thoracic Society statement, Lung Function testing.[13] This computer-suggested interpretation is an option that may be turned off in the configuration settings.

NOTE: If Interpretation is turned OFF in the Print Options configuration, the spirometer will not print the Comments heading.

Because data from poor patient efforts may result in false positive interpretations, careful analysis must be used in conjunction with the interpretations, especially when maneuver quality grades are low ("D" or "F" in Table 6 or Table 7). A flow chart of the interpretation algorithm results is shown in Table 8.

NOTE: The patient's height, birth date, and gender must be entered or no interpretation will be displayed.

Table 8: Interpretation Results



*Physiological variant is interpreted as "Undetermined" in the Renaissance II if FVC and FEV1 are greater than 100% and FEV1% is less than 100%.

If the FEV1/FVC ratio (FEV1%) is below the lower limit of the normal range, the patient is identified as having airway obstruction. The degree of obstruction is then determined by the amount of reduction in the FEV1 value. If the FVC is also reduced in a patient with an obstruction, a superimposed restriction cannot be ruled out.

When the FVC is below the lower limit of normal, and the FEV1% is normal, the patient may have a restrictive disorder. The degree of restriction can be determined by the amount of reduction in the FVC. Note that a low FVC is often due to poor patient effort. If both the FVC and FEV1% are within the normal range, the spirometry is considered to be normal.

NOTE: Refer to "Predicted Normal Equations and References" on page 60 for further explanation.

Lung Age Interpretation

Lung age is a smoking cessation tool that, if the option is enabled, appears on the Summary screen (by pressing the *RISK* soft key) and on the printed report (see *System Configuration* and *Spirometry Options (1)* starting on page 78 for information on how to enable the Lung Age option). The patient's lung age will be calculated if you have entered the patient's smoking history, and the patient's actual age is 20 to 84 years. The lung age value is calculated by substituting the predicted value of FEV1 with the smoker's actual FEV1. Then the FEV1 predicted equation is solved for age. The reported lung age value will never be less than 25 or less than the patient's actual age. It should be emphasized that the lung age parameter is intended to be used solely as a smoking cessation tool and not as a diagnostic measurement.[14]

NOTE: Entering a smoking cessation date will eliminate the lung age value.

Risk of COPD

The risk of COPD expresses the probability, expressed as a percentage, that the patient will develop Chronic Obstructive Pulmonary Disease (COPD) within the next 10 years and also provides an indication of the risk if the patient were to quit smoking. If the option is enabled, the COPD risk appears on the Summary screen (by pressing the *RISK* soft key) and on the printed report if the patient's age and smoking history were entered during new patient setup (see *System Configuration* and *Spirometry Options (1)* starting on page 78 for information on how to enable the Risk of COPD option). The risk of COPD is calculated using the patient's age, cigarettes smoked per day, measured FEV1, and predicted FEV1 as variables substituted into the equations documented in the article, *Risk of Chronic Obstructive Pulmonary Disease*.[15]

NOTE: The risk of COPD is calculated only for patients 64 years and younger.

Graphic Displays

Spirometry maneuvers are usually illustrated by means of graphs showing flow rates and volumes during expiration and inspiration. Two types of graphs are used, Flow-Volume (FV) and Volume-Time (VT). A typical Flow-Volume graph is shown in Figure 30. The Flow-Volume graph allows the user to easily evaluate whether the maneuver was poor due to a cough, slow start, poor effort or early termination. In addition, obstructive or restrictive disorders can often be detected by examining the waveform. Additional guidance can be obtained on this subject in the *Introduction to Spirometry Testing* section of this manual starting on page 15.

The Volume-Time Graph shown in Figure 31, is the traditional representation of the data. The advantage of this representation is that the FEV1 value, as well as most other timed parameters, can be read directly from the plot.

Either graph type can be viewed on the graphical display. In addition, the spirometer can be configured to print either, both, or none of the graphs.

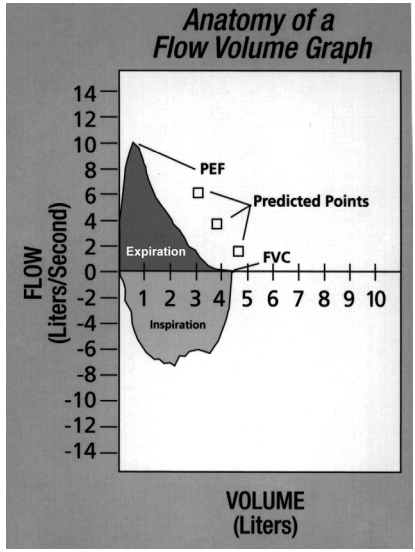


Figure 30: Flow-Volume Graph

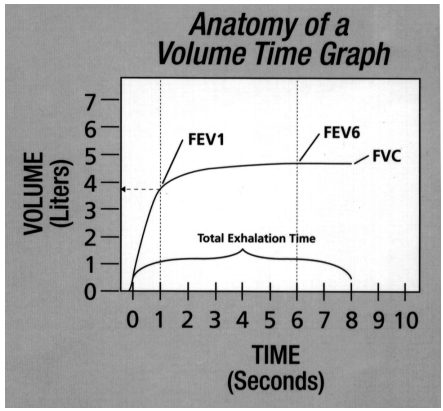


Figure 31: Volume-Time Graph

Service and Maintenance

Cleaning

Because the Renaissance II Spirometry System uses disposable single-patient use FSII flow sensors, there is no need to clean or sterilize any part of the spirometer or pressure tube.* Remove dust or fingerprints from the exterior by wiping with a damp cloth.

> ⚠ ***CAUTION:***
> ***Do not spray liquids on the Renaissance II System. Follow the cleaning instructions outlined in this section.***

If the need for a more thorough cleaning arises, the spirometer, base station, and tubing can be wiped down with a solution of 70% Isopropyl Alcohol or 10% bleach. Use the established procedures at your facility for the use and disposal of these disinfecting agents.

The pressure tube should be replaced at least once every year or if it becomes discolored or cracked. To remove the tube, grasp the thumb grip where it connects to the spirometer and pull gently until disconnected.

The spirometer's bar code reader may be cleaned by wrapping a flow sensor's bar coded tab with an alcohol wipe and sliding it through the bar code reader slot.

> ⚠ ***CAUTION:***
> ***Do not use the Renaissance II Spirometry System in areas of high humidity and dust, or in extreme environments.***

Warning

> ⚠ ***Chemicals from a broken LCD display panel are toxic when ingested. Use caution when handling a Renaissance II spirometer with a broken display panel.***

Battery Installation

The Renaissance II battery should be replaced at least once per year. Refer to the battery label to determine battery age. When there is a low battery condition (fewer than 20 patient tests can be performed), the Renaissance II spirometer beeps every 30 seconds and displays a low battery icon.

NOTE: Before replacing the battery, print the current configuration as indicated on page 86 to ensure no settings are lost.

*Contact Puritan Bennett Technical Support at 1.800.255.6774 for information regarding cross-contamination studies performed on the flow sensor and pressure tube.

Use the following procedure to install or replace the battery:

1. If the AC adapter is connected to the spirometer, remove the connector from the spirometer.
2. Remove the battery door (Figure 32) by pressing the tab on the front of the battery door and pulling the door off.
3. Remove the used NiCad battery pack by disconnecting the connector and lifting the batteries out gently.
4. Insert a new battery pack according to the illustration on inside of the case and plug in the connector.

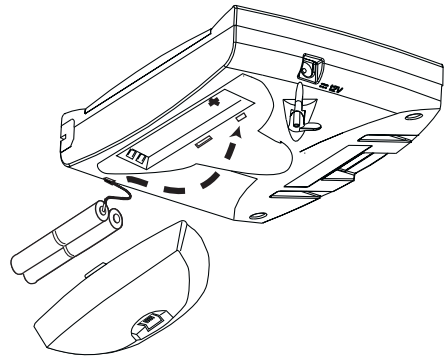


Figure 32: Battery Installation

5. After the batteries have been replaced, reinstall the battery door.
6. Charge the battery for at least 24 hours before portable use. Compare the System Configuration with your print-out to ensure settings are appropriate (see page 78 for System Configuration information).

The custom NiCad battery pack has a battery life of 10-12 hours in the ON position and a battery life of approximately 8 days in the OFF position.

Standard AA Alkaline or NiCad batteries may be used instead of the custom battery pack supplied with system. However, the Renaissance II will only charge the custom NiCad battery pack supplied with the unit.

NOTE: If the battery is removed, the unit will operate solely on AC power if connected to an electrical outlet via the AC adapter.

CAUTION:

- ***Dispose of batteries properly. Do not incinerate. Puritan Bennett recommends that customers or technical service personnel follow local governing ordinances and recycling instructions regarding disposal or recycling of batteries.***
- ***The NiCad battery pack or other batteries may discharge over time. Check batteries at least once per month for corrosion and verify batteries are fully charged. Store spirometer in charging base station to keep unit ready for use.***
- ***Remove batteries if spirometer will not be used for at least two weeks.***

Troubleshooting Guide

Unit powers up while on AC power, but not battery power

1. Verify that batteries are installed properly and properly charged.
2. Verify batteries are less than one year old. Replace batteries at least once per year.

NOTES:

- The Renaissance II Spirometry System is designed to recharge only the custom battery pack supplied with the system, and will not recharge batteries from other manufacturers.
- When there is a low battery condition, the Renaissance II spirometer beeps every 30 seconds and displays a low battery icon.

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3. Batteries may be low. Replace or recharge the custom battery pack.
4. Contact Puritan Bennett Technical Support if results are unsuccessful.

Unit does not power up on AC or battery power

1. Verify wall outlet or power strip is on and functioning properly. If not, try another outlet.
2. Verify power LEDs on spirometer and AC adapter illuminate.
3. Contact Puritan Bennett Technical Support if results are unsuccessful.

Unit powers up, but will not perform a test

1. If the spirometer failed the self test, record the error message, cycle power and try again.
2. If display does not illuminate, press several keys and note if unit beeps in response to key presses.
3. If the unit responds to key presses, the display contrast may have been adjusted incorrectly. From the "*MAIN*" screen, adjust contrast darker by pressing and holding the "*DARKER*" soft key (3rd key from left) until the display appears.
4. Contact Puritan Bennett Technical Support if results are unsuccessful.

"Error Reading Sensor" is displayed in the message window

1. Barcode strip is damaged or sensor swiped incorrectly. Swipe the sensor again or manually enter the six digit sensor calibration code.
2. Repeat the procedure with a new sensor.
3. Clean the spirometer's bar code reader by wrapping a flow sensor's bar coded tab with an alcohol wipe and sliding it through the bar code reader slot.
4. Contact Puritan Bennett Technical Support if results are unsuccessful.

Calibration error is more than ± 3%

1. Verify that the correct temperature is entered.
2. Verify that the correct barometric pressure or elevation for your location is entered.
3. If the percent error reading is -3% or less, check the system for leaks. Examine the pressure tube for any small punctures. Check syringe, sensor, and pressure tube for loose connections.
4. If the percent error is +3% or more, examine the flow sensor for foreign material contamination of the resistance medium.
5. Contact Puritan Bennett Technical Support if results are unsuccessful.

NOTE: Replace the pressure tube every year. Recertify 3-liter syringes once per year.

"Error Zeroing Sensor" is displayed in the message window

1. Movement sensed during zeroing. Place the sensor and pressure tube on the table top and repeat the procedure.
2. Disconnect the pressure tube from the spirometer and rezero. If the spirometer zeroes without the pressure tube connected, the pressure tube may be defective. Examine pressure tube for moisture or other obstruction in the clear portion of the tube.
3. Contact Puritan Bennett Technical Support if results are unsuccessful.

NOTE: Replace the pressure tube every year.

"Error Sensing Blast Out" is displayed in the message window

1. No exhalation was sensed within 20 seconds. Repeat the test.
2. Verify that the pressure tube is connected.
3. Examine pressure tube for damage.
4. Contact Puritan Bennett Technical Support if results are unsuccessful.

NOTE: Replace the pressure tube every year.

Spirometer auto-senses - (spirometer registers flow when no test is being performed)

1. Disconnect pressure tube and re-initiate a test procedure. If the unit does not auto-sense, replace the pressure tube.
2. If the unit auto-senses with nothing connected to it, contact Puritan Bennett Technical Support.

NOTE: Replace the pressure tube every year.

Patient test values displayed by the Renaissance II do not meet values expected by the physician.

If the values are unusually high:

1. Check for damage to the flow sensor.
2. Verify that the flow sensor is not contaminated with sputum or secretions.
3. Verify that the patient data (height, birth date, gender, ethnic origin) being used for the test is accurate for the patient.
4. If test is FVL, verify that proper room temperature and elevation or barometric pressure have been entered. (See Table 14 on page 87 in this User's Manual.)

NOTES:

- Overestimation of the room temperature will cause lung volume to be underestimated by 5%; conversely, if temperature is underestimated, lung volume will be overestimated.
- Verify that the displayed barometric pressure is correct. If not correct, there will be an error in the inspired volume (FIVC) during an FVL maneuver of approximately -1.3% for every 1,000 feet above sea level. Refer to the System Configuration section starting on page 78 for more information. The barometric pressure displayed is based on the initial elevation setting of the spirometer. However, the barometric pressure may be changed and the spirometer will, from that point on, use the new value entered.
- If you choose to obtain barometric pressure from an agency, such as the National Weather Service, verify that the value is NOT corrected to sea level.

5. Perform a calibration check using the sensor that the patient tested with. Make a note of the results.
6. Contact Puritan Bennett Technical Support if results are unsuccessful.

If the values are unusually low:

1. Check flow sensor and pressure tube for leaks.
2. Verify patient is not leaking air from mouth or nose. Use nose clips.
3. Verify patient is tightly closing lips and teeth around the outside of the sensor.

NOTE: Obstructing sensor opening with teeth, lips, or tongue while performing the test will cause low readings.

4. Perform a calibration check using the flow sensor that the patient tested with. Make a note of the results.
5. Contact Puritan Bennett Technical Support if results are unsuccessful.

NOTE: Replace the pressure tube every year.

Unable To Print Test Results

1. Verify that the printer is turned on and is online and ready.
2. Print a test page to ensure the printer is working properly. If the problem seems to be isolated to the printer, contact the printer manufacturer for technical support.
3. Verify that the proper printer has been selected in the spirometer's configuration. See *System Configuration* on page 78 and *Print Options (3)* on page 80 for information on configuring the printer.
4. Check the cable connections. When connecting the cable to the base station, verify that the thumbscrews have been tightened equally to provide a flush connection with the base station connector.
5. Verify that the spirometer was docked in the base station for the duration of printing.
6. Turn off the printer and remove the spirometer from the base station. Turn on the spirometer and place it in the base station. Turn the printer on. Attempt to print the test results.
7. Contact Puritan Bennett Technical Support if results are unsuccessful.

Electromagnetic Interference

The Renaissance II spirometer has been designed to provide reasonable protection against harmful interference in a typical medical environment. Because of the proliferation of radio frequency transmitting equipment and other sources of electrical noise in healthcare environments, however, it is possible that high levels of interference in close proximity may occur which could disrupt the performance of this device. The following is a list of possible types of radio frequency transmitting equipment and other sources of electrical noise sometimes present in healthcare environments:

- Electrosurgical units
- Cellular phones
- Mobile two-way radios

WARNING

⚠ ***When connecting the Renaissance II spirometer to any instrument, verify proper operation. Accessory equipment connected to the data interface must be certified according to IEC Standard 950 for data processing equipment or IEC Standard 601-1 for electromedical equipment. All combinations of equipment must be in compliance with IEC Standard 601-1-1 systems requirements. Anyone who connects additional equipment to the signal input port or signal output port, configures a medical system and is therefore responsible that the system complies with the requirements of IEC Standard 601-1-1 and the electromagnetic compatibility requirements of IEC Standard 601-1-2.***

During interference, the spirometer may not seem to operate correctly. Measurements may seem inappropriate, or there may be erratic readings, cessation of operation, or other incorrect functioning.

If erratic performance occurs, survey the location of the Renaissance II system to determine the source of the disruption, and take appropriate action as listed below:

- Turn other equipment in the vicinity off and on to isolate the problem.
- Reorient or relocate the offending device.
- Increase the separation between the interfering equipment and the spirometer.

If assistance is required, contact Puritan Bennett's Technical Support Department or your local Puritan Bennett representative.

> ⚠ ***CAUTION:***
> ***The Renaissance II system may be susceptible to radio frequency interference.***

Warranty Information

Refer to the warranty card(s) that came with your Renaissance II Spirometry System and accessories for specific warranty periods. If Puritan Bennett establishes a need of repair, another unit of comparable value will be dispatched as soon as possible. The foregoing warranty shall not apply and Puritan Bennett shall be relieved of any obligation or liability if the component has been:

- Repaired or altered, including the use of parts other than those manufactured or approved by Puritan Bennett
- Serviced by anyone other than Puritan Bennett
- Subjected to abuse, negligence, or accident
- Reused when sold for single-patient use only
- Connected to the wrong AC adapter

> ⚠ ***CAUTION:***
> ***Do not remove the cover of the Renaissance II spirometer or base station. Removal of the cover is permitted only by qualified service personnel. There are no user-serviceable parts inside.***

Puritan Bennett does not warrant accessories for the Renaissance II Spirometry System, such as the printer, that are not manufactured by or for Puritan Bennett. The end user is required to seek warranty assistance directly from the manufacturer of these accessories.

Also, the warranty may be voided if the system is used with any sensor other than those manufactured or licensed by Puritan Bennett for use with the Renaissance II Spirometry System. Please reference the warranty enclosed with your system for full clarification of the warranty.

Each Renaissance II spirometer and base station is manufactured and recorded with an individual serial number. The serial number is located on a label attached to the underside of the unit. Please reference this information when contacting Puritan Bennett.

NOTE: The serial numbers are located on a label affixed to the underside of the spirometer or base station. The first letter "G" represents the manufacturer. The next two numbers represent the year of manufacture. The two digits following the year represent either a base station (08) or a spirometer (07). The last five digits are sequential numbers assigned during manufacture.

Technical References

Table 9: Product Specifications Renaissance II Spirometer

Dimensions:	5.75"(H) x 7.5"(W) x 2.25" (D)
Weight:	18 ounces
Accuracy:*	Validated to comply with American Thoracic Society Standards for Spirometry (1994)[11]
Volume:	±3% of reading or 50 ml, whichever is greater; FEV1, FEV3 and FEV6 measured by back extrapolation
PEF:	±10% of reading or 0.40 L/sec, whichever is greater
FEF25-75% or MMEF:	±5% of reading or 0.20 L/sec, whichever is greater
Volume Range:	0-12 Liters BTPS
Flow Range:	±16 Liters/sec
Resistance:	Less than 1.5 cm H_2O /Liters/sec from 0-12 Liters/sec
Test Time:	SVC/FVC/FVL: 30 seconds; MVV: 15 seconds
Display:	3.1" x 2.4" viewable area (78mm x 61mm), 320 x 240 dots
Parameters Measured:	FVC, FEV1, FEV3, FEV6, FEV1/FVC (FEV1%), FEF25-75, FEF25, FEF50, FEF75, PEF, FET, VC, FVC Variability, FEV1 Variability, PEF Variability, FIVC, PIF, FEF50/FIF50%, MVV Time, MVV Rate, FVL, SVC
Memory Capacity:	Stores up to 1,000 patient tests
Adult Predicted Normal Values:	Knudson 1983, Knudson 1976, Crapo, Morris, NHANES III
Pediatric Predicted Normal Values:	Hsu, Polgar, Dockery, NHANES III
Interpretation Criteria:	American Thoracic Society, 1991. Lung Function Testing: *Selection of Reference Values and Interpretative Strategies. Am. Rev. Respir. Dis. 144.1202-1218, NHLEP*

*Contact Puritan Bennett Technical Support at 1.800.255.6774 for information regarding validation testing.

Table 9: Product Specifications Renaissance II Spirometer (cont.)

Battery:	6V rechargeable (600mAh min. capacity) NiCad battery pack, also supports 4 AA Alkaline batteries or NiCad batteries Charge life: 10-12 hrs. with unit turned ON; approx. 8 days with unit turned OFF *NOTE: Do not mix brands or types of batteries. Only the custom battery pack can be recharged using the AC adapter.*
Adapter/charger:	Output: 12VDC, 400mA Adapter Input: 120VAC/60 Hz/82mA/9.85VA IEC 601-1 Medical Grade compliant
Operating Temperature:	+17° to +40°C
Operating Humidity:	15% to 95% non-condensing
Operating Altitude: *	Up to 15,000 feet
Storage Temperature:	-20° to +60° C
Storage Humidity:	15% to 95% non-condensing
Storage Pressure:	500hPa to 1060hPa
Equipment Classification	Enclosure Degree of Protection from liquid ingress: IPX1 Applied Parts: Type BF Mode of Operation: Short-time operation Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or oxygen or nitrous oxide.

** Accuracy specifications are specified for 0-10,000 feet operation.*

Table 10: Product Specifications Renaissance II Base Station

Dimensions:	6.5"(H) x 4.75" (W) x 2.5"(D)
Weight:	8oz.
Interface:	Centronics-compatible IEEE 1284 parallel port for printer, custom RS-232 compatible connection for computer interface.
Printout:	8-1/2" X 11" or A4
Adapter/charger:	Output: 12VDC, 400mA Adapter Input: 120VAC/60Hz/52mA/9.55VA IEC 601-1 Medical Grade compliant

Table 10: Product Specifications Renaissance II Base Station (cont.)

Operating Temperature:	+17 to +40° C
Operating Humidity:	15% to 95% non-condensing
Operating Altitude:	Up to 15,000 feet
Storage Temperature:	-20° to +60° C
Storage Humidity:	15% to 95% non-condensing
Storage Pressure:	500hPa to 1060hPa
Equipment Classification	Applied Parts: Type BF Mode of Operation: Short-time operation Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or oxygen or nitrous oxide.

The FSII Single-Patient Use Flow Sensor

The Renaissance II Spirometry System uses Puritan Bennett's unique, individually calibrated, disposable FSII sensor. The single-patient use sensor eliminates the need to clean or sterilize any part of the spirometry system. The FSII sensor is designed for single-patient use only. This minimizes the effects of cross-contamination.

The FSII disposable sensor is used for all testing procedures. A 6-digit code is printed on the sensor in two forms:

- Numeric code
- Bar code

The code can be entered manually or by swiping the sensor through the bar code reader located on the spirometer. The sensor code contains information about the linearity characteristics of the sensor. The spirometer needs this information to accurately calculate the spirometric parameters. The numeric code is entered with each new patient, each time a calibration check is performed or anytime a new sensor is used. Your supply of sensors should be stored in a cool location. Each sensor should remain sealed in a plastic bag until ready for use.

CAUTION:

- ***Use only the FSII flow sensor specifically designed for the Renaissance II Spirometry System.***
- ***The FSII sensor is for single-patient use only. In the interest of environmental protection, dispose of all sensors and nose clips properly.***

Predicted Normal Equations and References

Patient's measured values are compared to their predicted values as one way of judging the degree of abnormality of their lung function. (*See references 1-10, 16 on page 91 of this User's Manual for the journal articles that describe the studies on which these equations are based.)*

WARNING

- ***Predicted values will be extrapolated for patients with age or height outside the age and/or height limits supported by the selected author's normal equations.***
- ***Results from spirometry testing should not be the sole source for determining a patient's diagnosis and treatment. Other clinical data, such as patient symptoms and respiratory history, should always be considered.***

NOTES:

- The patient's height, birth date, and gender must be entered or no interpretation will be displayed.
- Physiological variant is interpreted as "Undetermined" in the Renaissance II if FVC and FEV1 are greater than 100% and FEV1% is less than 100%.

Equation Variables

Hi = Height in inches

Hc = Height in centimeters

A = Age in years

LLN = lower limit of normal

Morris MALE

Limits age (18-90 years) height (58-80 inches)

FVC	-4.241 - 0.025A + 0.148Hi	(Morris, et al.,1971)
FVC(LLN)	FVC - (1.645 * 0.74)	(Morris, et al.,1971)
FEV1	-1.260 - 0.032A + 0.092Hi	(Morris, et al.,1971)
FEV1(LLN)	FEV1 - (1.645 * 0.55)	(Morris, et al.,1971)
FEV1%	107.12 - 0.2422A - 0.3118Hi	(Morris, et al.,1975)
FEV1%(LLN)	FEV1% - (1.645 * 7.79)	(Morris, et al.,1971)
FEV3	FVC * .95	(Morris, et al.,1971)
FEF25-75	2.513 - 0.045A + 0.047Hi	(Morris, et al.,1971)
FIVC	-4.241 - 0.025A + 0.148Hi	(Morris, et al.,1971)
MVV	-37.94893 - 0.81621A + 3.02915Hi	(Cherniack, et al.,1972)

Age < 25

PEF	-8.060 + 0.166A + 0.078Hc	(Knudson, et al.,1976)
FEV0.5	-3.054 + 0.043A + 0.030Hc	(Knudson, et al.,1976)
FEF50	-6.3851 + 0.1150A + 0.0543Hc	(Knudson, et al.,1983)
FEF75	-4.2421 - 0.0057A + 0.0397Hc	(Knudson, et al.,1983)

Age ≥ 25

PEF	-5.993 - 0.035A + 0.094Hc	(Knudson, et al.,1976)
FEV0.5	-2.746 - 0.017A + 0.037Hc	(Knudson, et al.,1976)
FEF50	-5.5409 - 0.0366A + 0.0684Hc	(Knudson, et al.,1983)
FEF75	-2.4827 - 0.0230A + 0.0310Hc	(Knudson, et al.,1983)

Morris FEMALE

Limits age (18-90 years) height (56-72 inches)

FVC	-2.852 - 0.024A + 0.115Hi	(Morris, et al.,1971)
FVC(LLN)	FVC - (1.645 * 0.52)	(Morris, et al.,1971)
FEV1	-1.932 - 0.025A + 0.089Hi	(Morris, et al.,1971)
FEV1(LLN)	FEV1 - (1.645 * 0.47)	(Morris, et al.,1971)
FEV1%	88.70 - 0.1815A - 0.0679Hi	(Morris, et al.,1975)
FEV1%(LLN)	FEV1% - (1.645 * 6.84)	(Morris, et al.,1971)
FEV3	FVC * 0.95	(Morris, et al.,1971)
FEF25-75	0.551 - 0.030A + 0.060Hi	(Morris, et al.,1971)
FIVC	-2.852 - 0.024A + 0.115Hi	(Morris, et al.,1971)
MVV	-4.86957 - 0.685A + 2.1384Hi	(Cherniack, et al.,1972)

Age < 20

PEF	-3.916 + 0.157A + 0.049Hc	(Knudson, et al.,1976)
FEV0.5	-1.738 + 0.061A + 0.019Hc	(Knudson, et al.,1976)
FEF50	-2.3040 + 0.1111A + 0.0288Hc	(Knudson, et al.,1983)
FEF75	-4.4009 + 0.2923A + 0.0243Hc	(Knudson, et al.,1983)
	-0.0075 * A^2	

Age ≥ 20

PEF	-0.735 - 0.025A + 0.049Hc	(Knudson, et al.,1976)
FEV0.5	-0.406 - 0.014A + 0.019Hc	(Knudson, et al.,1976)
FEF50	-0.4371 - 0.0240A + 0.0321Hc	(Knudson, et al.,1983)
FEF75	-0.1822 - 0.0254A + 0.0174Hc	(Knudson, et al.,1983)

Age ≥ 70

PEF	-0.735 - 0.025A + 0.049Hc	(Knudson, et al.,1976)
FEV0.5	-0.406 - 0.014A + 0.019Hc	(Knudson, et al.,1976)
FEF50	6.2402 - 0.0755A + 0.0118Hc	(Knudson, et al.,1983)
FEF75	1.8894 - 0.0172A	(Knudson, et al.,1983)

Knudson 1983 MALE

Limits age (18-85 years) height (58-80 inches)

Age < 25

FVC	-6.8865 + 0.0739A + 0.0590Hc	(Knudson, et al.,1983)
FVC(LLN)	0.798 * FVC	(Knudson, et al.,1983)
FEV1	-6.1181 + 0.0636A + 0.0519Hc	(Knudson, et al.,1983)
FEV1(LLN)	0.812 * FEV1	(Knudson, et al.,1983)
FEV3	-5.531 + 0.066A + 0.052Hc	(Knudson, et al.,1976)
FEV1%	92.8965 - 1.4612FVC	(Knudson, et al.,1983)
FEV1%(LLN)	0.848 * FEV1%	(Knudson, et al.,1983)
FEF25-75	-6.1990 + 0.0749A + 0.0539Hc	(Knudson, et al.,1983)
PEF	-8.060 + 0.166A + 0.078Hc	(Knudson, et al.,1976)
FIVC	-6.8865 + 0.0739A + 0.0590Hc	(Knudson, et al.,1983)
FEV0.5	-3.054 + 0.043A + 0.030Hc	(Knudson, et al.,1976)
FEF50	-6.3851 + 0.1150A + 0.0543Hc	(Knudson, et al.,1983)
FEF75	-4.2421 - 0.0057A + 0.0397Hc	(Knudson, et al.,1983)
MVV	-37.94893 - 0.81621A + 3.02915Hi	(Cherniack, et al.,1972)

Age ≥ 25

FVC	-8.7818 - 0.0298A + 0.0844Hc	(Knudson, et al.,1983)
FEV1	-6.5147 - 0.0292A + 0.0665Hc	(Knudson, et al.,1983)
FEV1%	96.3074 - 0.1677A - 1.4232FVC	(Knudson, et al.,1983)
FEV1%(LLN)	0.870 * FEV1%	(Knudson, et al.,1983)
FEV3	-5.245 - 0.031A + 0.063Hc	(Knudson, et al.,1976)
FEF25-75	-4.5175 - 0.0363A + 0.0579Hc	(Knudson, et al.,1983)
PEF	-5.993 - 0.035A + 0.094Hc	(Knudson, et al.,1976)
FIVC	-8.7818 - 0.0298A + 0.0844Hc	(Knudson, et al.,1983)
FEV0.5	-2.746 - 0.017A + 0.037Hc	(Knudson, et al.,1976)
FEF50	-5.5409 - 0.0366A + 0.0684Hc	(Knudson, et al.,1983)
FEF75	-2.4827 - 0.0230A + 0.0310Hc	(Knudson, et al.,1983)
MVV	-37.94893 - 0.81621A + 3.02915Hi	(Cherniack, et al.,1972)

Age > 25 and < 39

FVC(LLN)	0.811 * FVC	(Knudson, et al.,1983)
FEV1(LLN)	0.791 * FEV1	(Knudson, et al.,1983)

Age > 40

FVC(LLN)	0.734 * FVC	(Knudson, et al.,1983)
FEV1(LLN)	0.772 * FEV1	(Knudson, et al.,1983)

Knudson 1983 FEMALE

Limits age (18-88 years) height (56-72 inches)

Age < 20

FVC	-4.4470 + 0.0699A + 0.0416Hc	(Knudson, et al.,1983)
FVC(LLN)	0.749 * FVC	(Knudson, et al.,1983)
FEV1	-3.7622 + 0.0694A + 0.0351Hc	(Knudson, et al.,1983)
FEV1(LLN)	0.818 * FEV1	(Knudson, et al.,1983)
FEV3	-3.417 + 0.086A + 0.033Hc	(Knudson, et al.,1976)
FEV1%	91.9381 + 1.5226A - 7.7593FVC	(Knudson, et al.,1983)
FEV1%(LLN)	0.833 * FEV1%	(Knudson, et al.,1983)
FEF25-75	-2.8007 + 0.1275A + 0.0279Hc	(Knudson, et al.,1983)
PEF	-3.916 + 0.157A + 0.049Hc	(Knudson, et al.,1976)
FIVC	-4.4470 + 0.0699A + 0.0416Hc	(Knudson, et al.,1983)
FEV0.5	-1.738 + 0.061A + 0.019Hc	(Knudson, et al.,1976)
FEF50	-2.3040 + 0.1111A + 0.0288Hc	(Knudson, et al.,1983)
FEF75	-4.4009 + 0.2923A + 0.0243Hc -0.0075 * A^2	(Knudson, et al.,1983)
MVV	4.86957 - 0.685A + 2.1384Hi	(Cherniack, et al.,1972)

Age > 20 and < 70

FVC	-3.1947 - 0.0169A + 0.0444Hc	(Knudson, et al.,1983)
FEV1	-1.8210 - 0.0190A + 0.0332Hc	(Knudson, et al.,1983)
FEV3	-1.633 - 0.023A + 0.035Hc	(Knudson, et al.,1976)
FEV1%	113.694 - 0.2904A - 5.4024FVC	(Knudson, et al.,1983)
FEV1%(LLN)	0.854 * FEV1%	(Knudson, et al.,1983)
FEF25-75	-0.4057 - 0.0309A + 0.0300Hc	(Knudson, et al.,1983)
PEF	-0.735 - 0.025A + 0.049Hc	(Knudson, et al.,1976)
FIVC	-3.1947 - 0.0169A + 0.0444Hc	(Knudson, et al.,1983)
FEV0.5	-0.406 - 0.014A + 0.019Hc	(Knudson, et al.,1976)
FEF50	-0.4371 - 0.0240A + 0.0321Hc	(Knudson, et al.,1983)
FEF75	-0.1822 - 0.0254A + 0.0174Hc	(Knudson, et al.,1983)
MVV	-4.86957 - 0.685A + 2.1384Hi	(Cherniack, et al.,1972)

Age > 20 and < 39

FVC(LLN)	0.769 * FVC	(Knudson, et al.,1983)
FEV1(LLN)	0.703 * FEV1	(Knudson, et al.,1983)

Age > 40 and < 70

FVC(LLN)	0.752	(Knudson, et al.,1983)
FEV1(LLN)	0.779 * FEV1	(Knudson, et al.,1983)

Age ≥ 70

FVC	-0.1889 - 0.0296A + 0.0313Hc	(Knudson, et al.,1983)
FVC(LLN)	0.718 * FVC	(Knudson, et al.,1983)
FEV1	2.6539 - 0.0397A + 0.0143Hc	(Knudson, et al.,1983)
FEV1(LLN)	0.726 * FEV1	(Knudson, et al.,1983)
FEV3	-1.633 - 0.023A + 0.035Hc	(Knudson, et al.,1976)
FEV1%	113.694 - 0.2904A - 5.4024FVC	(Knudson, et al.,1983)
FEV1%(LLN)	0.854 * FEV1%	(Knudson, et al.,1983)
FEF25-75	6.3706 - 0.0615A	(Knudson, et al.,1983)
PEF	-0.735 - 0.025A + 0.049Hc	(Knudson, et al.,1976)
FIVC	-0.1889 - 0.0296A + 0.0313Hc	(Knudson, et al.,1983)
FEV0.5	-0.406 - 0.014A + 0.019Hc	(Knudson, et al.,1976)
FEF50	6.2402 -0.0755A + 0.0118Hc	(Knudson, et al.,1983)
FEF75	1.8894 -0.0172A	(Knudson, et al.,1983)
MVV	-4.86957 - 0.685A + 2.1384Hi	(Cherniack, et al.,1972)

Knudson 1976 Male

Limits age (18-85 years) height (58-80 inches)

Age < 25

FVC	-5.508 + 0.078A + 0.050Hc	(Knudson, et al.,1976)
FVC(LLN)	0.8150 * FVC	(Knudson, et al.,1976)
FEV1	-4.808 + 0.045A + 0.046Hc	(Knudson, et al.,1976)
FEV1(LLN)	0.8175 * FEV1	(Knudson, et al.,1976)
FEV3	-5.531 + 0.066A + 0.052Hc	(Knudson, et al.,1976)
FEV1%	103.64 - 0.140A - 0.087Hc	(Knudson, et al.,1976)
FEV1%(LLN)	0.8762 * FEV1%	(Knudson, et al.,1976)
FEF25-75	-5.334 + 0.059Hc	(Knudson, et al.,1976)
PEF	-8.060 + 0.166A + 0.078Hc	(Knudson, et al.,1976)
FIVC	-5.508 + 0.078A + 0.050Hc	(Knudson, et al.,1976)
FEV0.5	-3.054 + 0.043A + 0.030Hc	(Knudson, et al.,1976)
FEF50	-6.3851 + 0.1150A + 0.0543Hc	(Knudson, et al.,1983)
FEF75	-4.2421 - 0.0057A + 0.0397Hc	(Knudson, et al.,1983)
MVV	-37.94893 - 0.81621A + 3.02915Hi	(Cherniack, et al.,1972)

Age ≥ 25

FVC	-5.459 - 0.029A + 0.065Hc	(Knudson, et al.,1976)
FEV1	-4.203 - 0.027A + 0.052Hc	(Knudson, et al.,1976)
FEV3	-5.245 - 0.031A + 0.063Hc	(Knudson, et al.,1976)
FEV1%	103.64 - 0.140A - 0.087Hc	(Knudson, et al.,1976)
FEF25-75	-1.864 - 0.031A + 0.045Hc	(Knudson, et al.,1976)
PEF	-5.993 - 0.035A + 0.094Hc	(Knudson, et al.,1976)
FIVC	-5.459 - 0.029A + 0.065Hc	(Knudson, et al.,1976)
FEV0.5	-2.746 - 0.017A + 0.037Hc	(Knudson, et al.,1976)
FEF50	-5.5409 - 0.0366A + 0.0684Hc	(Knudson, et al.,1983)
FEF75	-2.4827 - 0.0230A + 0.0310Hc	(Knudson, et al.,1983)
MVV	-37.94893 - 0.81621A + 3.02915Hi	(Cherniack, et al.,1972)

Age > 25 and < 35

FVC(LLN)	0.8150 * FVC	(Knudson, et al.,1976)
FEV1(LLN)	0.8175 * FEV1	(Knudson, et al.,1976)
FEV1%(LLN)	0.8762 * FEV1%	(Knudson, et al.,1976)

Age > 35

FVC(LLN)	0.7446 * FVC	(Knudson, et al.,1976)
FEV1(LLN)	0.7292 * FEV1	(Knudson, et al.,1976)
FEV1%(LLN)	0.9188 * FEV1%	(Knudson, et al.,1976)

Knudson 1976 FEMALE

Limits age (18-88 years) height (56-72 inches)

Age < 20

FVC	-3.469 + 0.092A + 0.033Hc	(Knudson, et al.,1976)
FEV1	-2.703 + 0.085A + 0.027Hc	(Knudson, et al.,1976)
FEV3	-3.417 + 0.086A + 0.033Hc	(Knudson, et al.,1976)
FEV1%	107.38 - 0.109A - 0.111Hc	(Knudson, et al.,1976)
FEF25-75	-1.893 + 0.121A + 0.025Hc	(Knudson, et al.,1976)
PEF	-3.916 + 0.157A + 0.049Hc	(Knudson, et al.,1976)
FIVC	-3.469 + 0.092A + 0.033Hc	(Knudson, et al.,1976)
FEV0.5	-1.738 + 0.061A + 0.019Hc	(Knudson, et al.,1976)
FEF50	-2.3040 + 0.1111A + 0.0288Hc	(Knudson, et al.,1983)
FEF75	-4.4009 + 0.2923A + 0.0243Hc -0.0075 * A^2	(Knudson, et al.,1983)
MVV	-4.86957 - 0.685A + 2.1384Hi	(Cherniack, et al.,1972)

Age < 25

FVC(LLN)	0.7575 * FVC	(Knudson, et al.,1976)
FEV1(LLN)	0.7138 * FEV1	(Knudson, et al.,1976)
FEV1%(LLN)	0.8313 * FEV1%	(Knudson, et al.,1976)

Age > 25 and < 35

FVC(LLN)	0.7575 * FVC	(Knudson, et al.,1976)
FEV1(LLN)	0.7138 * FEV1	(Knudson, et al.,1976)
FEV1%(LLN)	0.8313 * FEV1%	(Knudson, et al.,1976)

Age > 35

FVC(LLN)	0.6646 * FVC	(Knudson, et al.,1983)
FEV1(LLN)	0.6940 * FEV1	(Knudson, et al.,1976)
FEV1%(LLN)	0.8806 * FEV1%	(Knudson, et al.,1976)

Age ≥ 20 and < 70

FVC	-1.774 - 0.022A + 0.037Hc	(Knudson, et al.,1976)
FEV1	-0.794 - 0.021A + 0.027Hc	(Knudson, et al.,1976)
FEV3	-1.633 - 0.023A + 0.035Hc	(Knudson, et al.,1976)
FEV1%	107.38 - 0.109A - 0.111Hc	(Knudson, et al.,1976)
FEF25-75	1.171 - 0.024A + 0.021Hc	(Knudson, et al.,1976)
PEF	-0.735 - 0.025A + 0.049Hc	(Knudson, et al.,1976)
FIVC	-1.774 - 0.022A + 0.037Hc	(Knudson, et al.,1976)
FEV0.5	-0.406 - 0.014A + 0.019Hc	(Knudson, et al.,1976)
FEF50	-0.4371 - 0.0240A + 0.0321Hc	(Knudson, et al.,1983)
FEF75	-0.1822 - 0.0254A + 0.0174Hc	(Knudson, et al.,1983)
MVV	-4.86957 - 0.685A + 2.1384Hi	(Cherniack, et al.,1972)

Age ≥ 70

FVC	-1.774 - 0.022A + 0.037Hc	(Knudson, et al.,1976)
FEV1	-0.794 - 0.021A + 0.027Hc	(Knudson, et al.,1976)
FEV3	-1.633 - 0.023A + 0.035Hc	(Knudson, et al.,1976)
FEV1%	107.38 - 0.109A - 0.111Hc	(Knudson, et al.,1976)
FEF25-75	1.171 - 0.024A + 0.021Hc	(Knudson, et al.,1976)
PEF	-0.735 - 0.025A + 0.049Hc	(Knudson, et al.,1976)
FIVC	-1.774 - 0.022A + 0.037Hc	(Knudson, et al.,1976)
FEV0.5	-0.406 - 0.014A + 0.019Hc	(Knudson, et al.,1976)
FEF50	6.2402 - 0.0755A + 0.0118Hc	(Knudson, et al.,1983)
FEF75	1.8894 - 0.0172A	(Knudson, et al.,1983)
MVV	-4.86957 - 0.685A + 2.1384Hi	(Cherniack, et al.,1972)

Crapo MALE

Limits age (18-89 years) height (61-77 inches)

FVC	-4.650 - 0.0214A + 0.0600Hc	(Crapo, et al.,1981)
FVC(LLN)	FVC - 1.115	(Crapo, et al.,1981)
FEV1	-2.190 - 0.0244A + 0.0414Hc	(Crapo, et al.,1981)
FEV1(LLN)	FEV1 - 0.842	(Crapo, et al.,1981)
FEV3	-3.512 - 0.0271A + 0.0535Hc	(Crapo, et al.,1981)
FEF25-75	2.133 - 0.0380A + 0.0204Hc	(Crapo, et al.,1981)
FEV1%	110.49 - 0.1520A - 0.1300Hc	(Crapo, et al.,1981)
FEV1%(LLN)	FEV1% - 8.28	(Crapo, et al.,1981)
FEV0.5	-1.914 - 0.0152A + 0.0327Hc	(Crapo, et al.,1981)
FIVC	-4.650 - 0.0214A + 0.0600Hc	(Crapo, et al.,1981)
MVV	-37.94893 - 0.81621A + 3.02915Hi	(Cherniack, et al.,1972)

Age < 25

PEF	-8.060 + 0.166A + 0.078Hc	(Knudson, et al.,1976)
FEF50	-6.3851 + 0.1150A + 0.0543Hc	(Knudson, et al.,1983)
FEF75	-4.2421 - 0.0057A + 0.0397Hc	(Knudson, et al.,1983)

Age ≥ 25

PEF	-5.993 - 0.035A + 0.094Hc	(Knudson, et al.,1976)
FEF50	-5.5409 - 0.0366A + 0.0684Hc	(Knudson, et al.,1983)
FEF75	-2.4827 - 0.0230A + 0.0310Hc	(Knudson, et al.,1983)

Crapo FEMALE

Limits age (18-89 years) height (57-70 inches)

FVC	-3.590 - 0.0216A + 0.0491Hc	(Crapo, et al.,1981)
FVC(LLN)	FVC - 0.676	(Crapo, et al.,1981)
FEV1	-1.578 - 0.0255A + 0.0342Hc	(Crapo, et al.,1981)
FEV1(LLN)	FEV1 - 0.561	(Crapo, et al.,1981)
FEV3	-2.745 - 0.0257A + 0.0442Hc	(Crapo, et al.,1981)
FEF25-75	2.683 - 0.0460A + 0.0154Hc	(Crapo, et al.,1981)
FEV1%	126.58 - 0.2520A - 0.2020Hc	(Crapo, et al.,1981)
FEV1%(LLN)	FEV1% - 9.06	(Crapo, et al.,1981)
FEV0.5	-0.809 - 0.0185A + 0.0238Hc	(Crapo, et al.,1981)
FIVC	-3.590 - 0.0216A + 0.0491Hc	(Crapo, et al.,1981)
MVV	-4.86957- 0.685A + 2.1384Hi	(Cherniack, et al.,1972)

Age < 20

PEF	-3.916 + 0.157A + 0.049Hc	(Knudson, et al.,1976)
FEF50	-2.3040 + 0.1111A + 0.0288Hc	(Knudson, et al.,1983)
FEF75	-4.4009 + 0.2923A + 0.0243Hc -0.0075 * A^2	(Knudson, et al.,1983)

Age ≥ 20 and < 70

PEF	-0.735 - 0.025A + 0.049Hc	(Knudson, et al.,1976)
FEF50	-0.4371 - 0.0240A + 0.0321Hc	(Knudson, et al.,1983)
FEF75	-0.1822 - 0.0254A + 0.0174Hc	(Knudson, et al.,1983)

Age ≥ 70

PEF	-0.735 - 0.025A + 0.049Hc	(Knudson, et al.,1976)
FEF50	6.2402 -0.0755A + 0.0118Hc	(Knudson, et al.,1983)
FEF75	1.8894 -0.0172A	(Knudson, et al.,1983)

Hsu MALE

Limits age (7-17 years) height (43-75 inches)

FVC	3.58 * 10^-7 * Hc^3.18	(Hsu, et al.,1979)
FVC(LLN)	FVC * ((1.0 - 0.13)^2)	(Hsu, et al.,1979)
FEV1	7.74 * 10^-7 * Hc^3.00	(Hsu, et al.,1979)
FEV1(LLN)	FEV1 * ((1.0 - 0.13) ^2)	(Hsu, et al.,1979)

FEF25-75	1.33 * 10^-5 * Hc^2.46	(Hsu, et al.,1979)
PEF	5.58 * 10^-6 * Hc^2.79	(Hsu, et al.,1979)
FEV1%	(PRED FEV1/PRED FVC) 100	(Hsu, et al.,1979)
FEV1%(LLN)	0.90 * FEV1%	(Hsu, et al.,1979)
FIVC	3.58 * 10^-7 * Hc^3.18	(Hsu, et al.,1979)

FEV0.5	.7778 * FEV1	(Hsu, et al.,1979)
FEV3	.98 * FVC	(Hsu, et al.,1979)
MVV	-99.507 +1.267Hc	(Polgar, et al.,1971)

Age < 12

FEF50	-2.5454 + 0.0378Hc	(Knudson, et al.,1983)
FEF75	-1.0149 + 0.0171Hc	(Knudson, et al.,1983)

Age ≥ 12

FEF50	-6.3851 + 0.1150A + 0.0543Hc	(Knudson, et al.,1983)
FEF75	-4.2421 - 0.0057A + 0.0397Hc	(Knudson, et al.,1983)

Hsu FEMALE

Limits age (7-17 years) height (43-71 inches)

FVC	2.57 * 10^-6 * Hc^2.78	(Hsu, et al.,1979)
FVC(LLN)	FVC * ((1.0 - 0.14)^2)	(Hsu, et al.,1979)
FEV1	3.79 * 10^-6 * Hc^2.68	(Hsu, et al.,1979)
FEV1(LLN)	FEV1 * ((1.0 - 0.14) ^2)	(Hsu, et al.,1979)
FEF25-75	6.32 * 10^-5 * Hc^2.16	(Hsu, et al.,1979)
PEF	4.30 * 10^-5 * Hc^2.37	(Hsu, et al.,1979)
FEV1%	(PRED FEV1/PRED FVC) 100	(Hsu, et al.,1979)
FEV1%(LLN)	0.90 * FEV1%	(Hsu, et al.,1979)
FIVC	2.57 * 10^-6 * Hc^2.78	(Hsu, et al.,1979)
FEV0.5	.7778 * FEV1	(Hsu, et al.,1979)
FEV3	.98 * FVC	(Hsu, et al.,1979)
MVV	-99.507 +1.267Hc	(Polgar, et al.,1971)

Age < 11

FEF50	0.7362 + 0.1846A	(Knudson, et al.,1983)
FEF75	-0.1657 + 0.0109Hc	(Knudson, et.al.,1983)

Age ≥ 11

FEF50	-2.3040 + 0.1111A + 0.0288Hc	(Knudson, et al.,1983)
FEF75	-4.4009 + 0.2923A + 0.0243Hc -0.0075 * A^2	(Knudson, et al.,1983)

Polgar MALE

Limits age (4-17 years) height (43-67 inches)

FVC	4.4 * 10^-6 * Hc^2.67	(Polgar, et al.,1971)
FVC(LLN)	FVC * (1 - (1.645 * 0.13))	(Polgar, et al.,1971)
FEV1	2.1 * 10^-6 * Hc^2.80	(Polgar, et al.,1971)
FEV1(LLN)	FEV1 * (1 - (1.645 * 0.088))	(Polgar, et al.,1971)
FEF25-75	-3.4616 + 0.0437 Hc	(Polgar, et al.,1971)
PEF	-7.0929 + .08738 Hc	(Polgar, et al.,1971)
FEV1%	47.73 * Hc^.13	(Polgar, et al.,1971)
FEV1%(LLN)	0.90 * FEV1%	(Polgar, et al.,1971)
FIVC	4.4 * 10^-6 * Hc^2.67	(Polgar, et al.,1971)
FEV0.5	.7778 * FEV1	(Polgar, et al.,1971)
FEV3	.98 * FVC	(Polgar, et al.,1971)
MVV	-99.507 +1.267Hc	(Polgar, et al.,1971)

Age < 12

FEF50	-2.5454 + 0.0378Hc	(Knudson, et al.,1983)
FEF75	-1.0149 + 0.0171Hc	(Knudson, et al.,1983)

Age ≥ 12

FEF50	-6.3851 + 0.1150A + 0.0543Hc	(Knudson, et al.,1983)
FEF75	-4.2421 - 0.0057A + 0.0397Hc	(Knudson, et al.,1983)

Polgar FEMALE

Limits age (4-17 years) height (43-67 inches)

FVC	3.3 * 10^-6 * Hc^2.72	(Polgar, et al.,1971)
FVC(LLN)	FVC * (1 - (1.645 * 0.13))	(Polgar, et al.,1971)
FEV1	2.1 * 10^-6 * Hc^2.80	(Polgar, et al.,1971)
FEV1(LLN)	FEV1 * (1 - (1.645 * 0.088))	(Polgar, et al.,1971)
FEF25-75	-3.4616 + 0.0437 Hc	(Polgar, et al.,1971)
PEF	-7.0929 + .08738 Hc	(Polgar, et al.,1971)
FEV1%	63.63 * Hc^.08	(Polgar, et al.,1971)
FEV1%(LLN)	0.90 * FEV1%	(Polgar, et al.,1971)
FIVC	3.3 * 10^-6 * Hc^2.72	(Polgar, et al.,1971)
FEV0.5	.7778 * FEV1	(Polgar, et al.,1971)
FEV3	.98 * FVC	(Polgar, et al.,1971)
MVV	-99.507 +1.267Hc	(Polgar, et al.,1971)

Age < 11

FEF50	0.7362 + 0.1846A	(Knudson, et al.,1983)
FEF75	-0.1657 + 0.0109Hc	(Knudson, et al.,1983)

Age ≥ 11

FEF50	-2.3040 + 0.1111A + 0.0288Hc	(Knudson, et al.,1983)
FEF75	-4.4009 + 0.2923A + 0.0243Hc -0.0075 * A^2	(Knudson, et al.,1983)

NHANES III MALE
(Hankinson, et al.,1999)

Caucasian
Age < 20

FEV1	-0.7453 - 0.04106A + 0.004477 * A^2 + 0.00014098 * Hc^2
FEV1(LLN)	-0.7453 - 0.04106A + 0.004477 * A^2+ 0.00011607 * Hc^2
FEV6	-0.3119 - 0.18612A + 0.009717 * A^2 + 0.00018188 * Hc^2
FEV6(LLN)	-0.3119 - 0.18612A + 0.009717 * A^2 + 0.00015323 * Hc^2
FVC	-0.2584 - 0.20415A + 0.010133 * A^2 + 0.00018642 * Hc^2
FVC(LLN)	-0.2584 - 0.20415A + 0.010133 * A^2 + 0.00015695 * Hc^2
PEF	-0.5962 - 0.12357A + 0.013135 * A^2 + 0.00024962 * Hc^2
PEF(LLN)	-0.5962 - 0.12357A + 0.013135 * A^2 + 0.00017635 * Hc^2
FEF25-75	-1.0863 + 0.13939A + 0.00010345 * Hc^2
FEF25-75(LLN)	-1.0863 + 0.13939A + 0.00005294 * Hc^2

Caucasian
Age > 20

FEV1	0.5536 - 0.01303A + 0.000172 * A^2 + 0.00014098 * Hc^2
FEV1(LLN)	0.5536 - 0.01303A + 0.000172 * A^2 + 0.00011607 * Hc^2
FEV6	0.1102 - 0.00842A - 0.000223 * A^2 + 0.00018188 * Hc^2
FEV6(LLN)	0.1102 - 0.00842A - 0.000223 * A^2 + 0.00015323 * Hc^2
FVC	-0.1933 + 0.00064A - 0.000269 * A^2 + 0.00018642 * Hc^2
FVC(LLN)	-0.1933 + 0.00064A - 0.000269 * A^2 + 0.00015695 * Hc^2
PEF	1.0523+ 0.08272A - 0.001301 * A^2 + 0.00024962 * Hc^2
PEF(LLN)	1.0523 + 0.08272A - 0.001301 * A^2 + 0.00017635 * Hc^2
FEF25-75	2.7006 - 0.04995A + 0.00010345 * Hc^2
FEF25-75 (LLN)	2.7006 - 0.04995A + 0.00005294 * Hc^2

African-American
Age < 20

FEV1	-0.7048 - 0.05711A + 0.004316 * A^2 + 0.00013194 * Hc^2
FEV1(LLN)	-0.7048 - 0.05711A + 0.004316 * A^2 + 0.00010561 * Hc^2
FEV6	-0.5525 - 0.14107A + 0.007241 * A^2 + 0.00016429 * Hc^2
FEV6(LLN)	-0.5525 - 0.14107A + 0.007241 * A^2 + 0.00013499 * Hc^2
FVC	-0.4971- 0.15497A + 0.007701 * A^2 + 0.00016643 * Hc^2
FVC(LLN)	-0.4971- 0.15497A + 0.007701 * A^2 + 0.00013670 * Hc^2
PEF	-0.2684 - 0.28016A + 0.018202 * A^2 + 0.00027333 * Hc^2
PEF(LLN)	-0.2684 - 0.28016A + 0.018202 * A^2 + 0.00018938 * Hc^2

FEF25-75 -1.1627 + 0.12314A + 0.00010461 * Hc^2
FEF25-75(LLN) -1.1627 + 0.12314A + 0.00004819 * Hc^2

African-American
Age > 20

FEV1 0.3411- 0.02309A + 0.00013194 * Hc^2
FEV1(LLN) 0.3411- 0.02309A + 0.00010561 * Hc^2

FEV6 -0.0547- 0.02114A + 0.00016429 * Hc^2
FEV6(LLN) -0.0547- 0.02114A + 0.00013499 * Hc^2

FVC -0.1517 - 0.01821A + 0.00016643 * Hc^2
FVC(LLN) -0.1517 - 0.01821A + 0.00013670 * Hc^2
PEF 2.2257 - 0.04082A + 0.00027333 * Hc^2
PEF(LLN) 2.2257 - 0.04082A + 0.00018938 * Hc^2

FEF25-75 2.1477- 0.04238A + 0.00010461 * Hc^2
FEF25-75(LLN) 2.1477- 0.04238A + 0.00004819 * Hc^2

Mexican-American
Age < 20

FEV1 -0.8218 - 0.04248A + 0.004291 * A^2 + 0.00015104 * Hc^2
FEV1(LLN) -0.8218 - 0.04248A + 0.004291 * A^2 + 0.00012670 * Hc^2

FEV6 -0.6646 - 0.11270A + 0.007306 * A^2 + 0.00017840 * Hc^2
FEV6(LLN) -0.6646 - 0.11270A + 0.007306 *A^2 + 0.00015029 * Hc^2

FVC -0.7571- 0.09520 A + 0.006619 * A^2+ 0.00017823 * Hc^2
FVC(LLN) -0.7571- 0.09520 A + 0.006619 * A^2 + 0.00014947 * Hc^2

PEF -0.9537- 0.19602 A + 0.014497 * A^2+ 0.00030243 * Hc^2
PEF(LLN) -0.9537- 0.19602 A + 0.014497 * A^2 + 0.00021833 * Hc^2

FEF25-75 -1.3592 + 0.10529A + 0.00014470 * Hc^2
FEF25-75(LLN) -1.3592 + 0.10529A + 0.00009020 * Hc^2

Mexican-American
Age > 20

FEV1 0.6306 - 0.02928A + 0.00015104 * Hc^2
FEV1 (LLN) 0.6306 - 0.02928A + 0.00012670 * Hc^2
FEV6 0.5757 - 0.02860A + 0.00017840 * Hc^2
FEV6 (LLN) 0.5757 - 0.02860A + 0.00015029 * Hc^2
FVC 0.2376 - 0.00891A - 0.000182 * A^2 + 0.00017823 * Hc^2
FVC (LLN) 0.2376 - 0.00891A - 0.000182 * A^2 + 0.00014947 * Hc^2

PEF	0.0870 + 0.06580A - 0.001195 * A^2 + 0.00030243 * Hc^2
PEF(LLN)	0.0870 + 0.06580A - 0.001195 * A^2 + 0.00021833 * Hc^2
FEF25-75	1.7503 - 0.05018A + 0.00014473 * Hc^2
FEF25-75(LLN)	1.7503 - 0.05018A + 0.00009020 * Hc^2

NHANES III FEMALE
(Hankinson, et al.,1999)
Caucasian
Age < 18

FEV1	-0.8710 + 0.06537A + 0.00011496 * Hc^2
FEV1(LLN)	-0.8710 + 0.06537A + 0.00009283 * Hc^2
FEV6	-1.1925 +0.06544A + 0.00014395 * Hc^2
FEV6(LLN)	-1.1925 +0.06544A + 0.00011827 * Hc^2
FVC	-1.2082 + 0.0591A + 0.00014815 * Hc^2
FVC(LLN)	-1.2082 + 0.0591A + 0.00012198 * Hc^2
PEF	-3.6181 + 0.60644A - 0.016846 * A^2 + 0.00018623 * Hc^2
PEF(LLN)	-3.6181 + 0.60644A - 0.016846 * A^2 + 0.00012148 * Hc^2
FEF25-75	-2.5284 + 0.52490A - 0.015309 * A^2 + 0.00006982 * Hc^2
FEF25-75(LLN)	-2.5284 + 0.52490A - 0.015309 * A^2 + 0.00002302 * Hc^2

Caucasian
Age >18

FEV1	0.4333 - 0.00361A - 0.000194 * A^2 + 0.00011496 * Hc^2
FEV1(LLN)	0.4333 - 0.00361A - 0.000194 * A^2 + 0.00009283 * Hc^2
FEV6	-0.1373 + 0.01317A - 0.000352 * A^2 + 0.00014395 * Hc^2
FEV6(LLN)	-0.1373 + 0.01317A - 0.000352 * A^2 + 0.00011827 * Hc^2
FVC	-0.3560 + 0.01870A - 0.000382 * A^2 + 0.00014815 * Hc^2
FVC(LLN)	-0.3560 + 0.01870A - 0.000382 * A^2 + 0.00012198 * Hc^2
PEF	0.9267 + 0.06929A - 0.001031 * A^2 + 0.00018623 * Hc^2
PEF(LLN)	0.9267 + 0.06929A - 0.001031 * A^2 + 0.00012148 * Hc^2
FEF25-75	2.3670 - 0.01904A - 0.000200 * A^2 + 0.00006982 * Hc^2
FEF25-75(LLN)	2.3670 - 0.01904A - 0.000200 * A^2 + 0.00002302 * Hc^2

African-American
Age < 18

FEV1 - 0.9630 + 0.05799A + 0.00010846 * Hc^2
FEV1(LLN) - 0.9630 + 0.05799A + 0.00008546 * Hc^2

FEV6 - 0.6370 - 0.04243A + 0.003508 * A^2 + 0.00013497 * Hc^2
FEV6(LLN) - 0.6370 - 0.04243A + 0.003508 * A^2 + 0.00010848 * Hc^2

FVC -0.6166 - 0.04687 A + 0.003602 * A^2 + 0.00013606 * Hc^2
FVC(LLN) -0.6166 - 0.04687 A + 0.003602 * A^2 + 0.00010916 * Hc^2

PEF -1.2398 + 0.163750A + .000109746 * Hc^2
PEF(LLN) -1.2398 + 0.163750A + 0.00012160 * Hc^2

FEF25-75 -2.5379 + 0.43755A - 0.012154 * A^2 + 0.00008572 * Hc^2
FEF25-75(LLN) -2.5379 + 0.43755A - 0.012154 * A^2 + 0.00003380 * Hc^2

African-America
Age > 18

FEV1 0.3433 - 0.01283A - 0.000097 * A^2 + 0.00010846 * Hc^2
FEV1(LLN) 0.3433 - 0.01283A - 0.000097 * A^2 + 0.00008546 * Hc^2

FEV6 -0.1981 + 0.00047A - 0.000230 * A^2 + 0.00013497 * Hc^2
FEV6(LLN) -0.1981 + 0.00047A - 0.000230 * A^2 + 0.00010848 * Hc^2

FVC -0.3039 + 0.00536A - 0.000265 * A^2 + 0.00013606 * Hc^2
FVC(LLN) -0.3039 + 0.00536A - 0.000265 * A^2 + 0.00010916 * Hc^2

PEF 1.3597 + 0.03458A - 0.000847 * A^2 + 0.00019746 * Hc^2
PEF (LLN) 1.3597 + 0.03458A - 0.000847 * A^2 + 0.00012160 * Hc^2

FEF25-75 2.0828 - 0.03793A + 0.00008572 * Hc^2
FEF25-75(LLN) 2.0828 - 0.03793A + 0.00003380 * Hc^2

Mexican-American
Age < 18

FEV1 -0.9641 + 0.06490 A + 0.00012154 * Hc^2
FEV1(LLN) -0.9641 + 0.06490 A + 0.00009890 * Hc^2

FEV6 -1.2410 + 0.07625A + 0.00014106 * Hc^2
FEV6 (LLN) -1.2410 + 0.07625A + 0.00011480 * Hc^2
FVC -1.2507 + 0.07501A + 0.00014246 * Hc^2
FVC (LLN) -1.2507 + 0.07501A + 0.00011570 * Hc^2
PEF -3.2549 + 0.47495A - 0.013193 * A^2 + 0.00022203 * Hc^2
PEF(LLN) -3.2549 + 0.47495A - 0.013193 * A^2 + 0.00014611 * Hc^2

FEF25-75	-2.1825 + 0.42451A - 0.012415 * A^2 + 0.00009610 * Hc^2
FEF25-75(LLN)	-2.1825 + 0.42451A - 0.012415 * A^2 + 0.00004594 * Hc^2

Mexican-American
Age > 18

FEV1	0.4529 - 0.01178A - 0.000113 * A^2 + 0.00012154 * Hc^2
FEV1(LLN)	0.4529 - 0.01178A - 0.000113 * A^2 + 0.00009890 * Hc^2
FEV6	0.2033 + 0.00020A - 0.000232 * A^2 + 0.00014106 * Hc^2
FEV6(LLN)	0.2033 + 0.00020A - 0.000232 * A^2 + 0.00011480 * Hc^2
FVC	0.1210 + 0.00307A - 0.000237 * A^2 + 0.00014246 * Hc^2
FVC (LLN)	0.1210 + 0.00307A - 0.000237 * A^2 + 0.00011570 * Hc^2
PEF	0.2401 + 0.06174A - 0.001023 * A^2 + 0.00022203 * Hc^2
PEF(LLN)	0.2401 + 0.06174A - 0.001023 * A^2 + 0.00014611 * Hc^2
FEF25-75	1.7456 - 0.0119A + 0.000291 * A^2 + 0.00009610 * Hc^2
FEF25-75(LLN)	1.7456 - 0.0119A + 0.000291 * A^2 + 0.00004594 * Hc^2

Dockery
(Wang, Dockery, et al., 1993)

The regression model is: x = exp (a + b ln (H)), where x is FVC(L), FEV1(L), FEV1% or FEF25-75 (L/s), H is height in meters, and a and b are constants listed in the tables.

MALE Caucasian
Age 6-17

AGE	*FVC*		*FEV1*		*FEV1%*		*FEF25-75*	
	a	b	a	b	a	b	a	b
6	-0.024	2.470	-0.109	2.252	-0.078	-0.248	_	_
7	-0.018	2.489	-0.104	2.270	-0.086	-0.220	_	_
8	0.005	2.443	-0.089	2.257	-0.091	0.199	0.264	1.505
9	0.017	2.426	-0.063	2.197	-0.086	-0.206	0.308	1.443
10	0.030	2.407	-0.057	2.212	-0.081	-0.209	0.290	1.557
11	0.009	2.468	-0.093	2.324	-0.101	-0.147	0.242	1.738
12	-0.061	2.649	-0.161	2.512	-0.101	-0.133	0.165	1.982
13	-0.175	2.924	-0.292	2.843	-0.116	-0.085	0.007	2.396
14	-0.219	3.060	-0.329	2.983	-0.106	-0.087	0.014	2.483
15	-0.079	2.859	-0.141	2.709	-0.060	-0.155	0.241	2.163
16	0.104	2.591	0.062	2.409	-0.045	-0.178	0.503	1.764
17	0.253	2.374	0.262	2.099	0.008	-0.272	0.762	1.368

Dockery
(Wang, Dockery, et al., 1993)
FEMALE Caucasian
Age 6-17

AGE	*FVC*		*FEV1*		*FEV1%*		*FEF25-75*	
	a	b	a	b	a	b	a	b
6	-0.013	2.007	0.109	1.949	-0.097	-0.055	_	_
7	-0.062	2.385	-0.144	2.243	-0.08	-0.132	_	_
8	-0.055	2.381	-0.137	2.239	-0.079	-0.152	0.247	1.668
9	-0.039	2.351	-0.123	2.222	-0.084	-0.128	0.254	1.710
10	-0.068	2.458	-0.161	2.364	-0.092	-0.097	0.195	1.933
11	-0.120	2.617	-0.223	2.558	-0.102	-0.061	0.161	2.091
12	-0.174	2.776	-0.264	2.709	-0.090	-0.067	0.185	2.120
13	-0.061	2.576	-0.153	2.535	-0.093	-0.040	0.294	1.976
14	0.139	2.208	0.046	2.178	-0.096	-0.026	0.450	1.711
15	0.210	2.099	0.148	2.008	-0.062	-0.093	0.581	1.486
16	0.226	2.097	0.181	1.972	-0.048	-0.120	0.654	1.366
17	0.214	2.146	0.176	1.992	-0.038	-0.154	0.688	1.290

Dockery MALE
(Wang, Dockery, et al., 1993)

FVC(LLN)	0.830 * FVC
FEV1(LLN)	0.825 * FEV1
FEV1%(LLN)	0.890 * FEV1%

Dockery FEMALE
(Wang, Dockery, et al., 1993)

FVC(LLN)	0.822 * FVC
FEV1(LLN)	0.823 * FEV1
FEV1%(LLN)	0.895 * FEV1%

NOTE: The studies upon which these equations are based were not conducted by Puritan Bennett. The appropriate regulatory agencies should be consulted for independent validation.

RS-232 Interface Specifications

The Renaissance II Spirometry System supports asynchronous communications to a computer system via a RS-232C compatible serial port. Data can be transmitted from the spirometer only when it is docked in the base station. The interface connection on the base station is a standard 25-pin IBM PC-AT style connector. The pin locations for this connector are shown in Figure 33. Puritan Bennett recommends using a null modem cable to connect the spirometer base station to a PC.

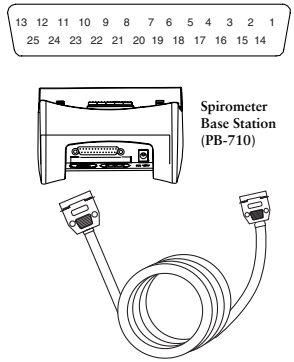

Figure 33: Pin locations (base station)

Pin Function Descriptions

The function of the pins is described in Pin Function Descriptions (Table 11). Pins 12, 13, 14, 16 and 18 are used for RS-232 communications for remote control of the spirometer. All other pins are used for printer interfacing via standard IEEE 1284 printer cable.

Table 11: Pin Function Descriptions

1	To Printer	Data Strobe
2	To Printer	Printer Data Bit 0
3	To Printer	Printer Data Bit 1
4	To Printer	Printer Data Bit 2
5	To Printer	Printer Data Bit 3
6	To Printer	Printer Data Bit 4
7	To Printer	Printer Data Bit 5
8	To Printer	Printer Data Bit 6
9	To Printer	Printer Data Bit 7
10	To Base	Printer ACK
11	To Base	Printer Busy
12	To Base	RS232 Clear To Send
13	To Base	RS232 Receive Data

Table 11: Pin Function Descriptions (cont.)

14	To PC	RS232 Request To Send
15	To Base	Printer Error
16	To PC	RS 232 Transmit Data
17	To Printer	Printer Select
18, 19		Ground
20		Ground
21		Ground
22		Ground
23, 24, 25		Ground

In order for the computer system to communicate successfully with the Renaissance II Spirometry System, an application program must first be written on the computer system. This program must do more than act as a "terminal" because the Renaissance II system requires responses from the computer for setting up the proper handshaking.

Using the Renaissance II with a PC and Dataflow™ Software

Patient data can be stored and managed on a PC that has optional *DataFlow*™ Data Management Software installed. *DataFlow* software enables data transfer to and from the Renaissance II spirometer via a null modem cable connected between the PC and the spirometer base. *DataFlow* software allows you to:

- Examine trends in patient pulmonary function
- Update the spirometer with changes to patient data
- Print reports from your computer
- Query the database
- Archive data in a database

Contact Puritan-Bennett Customer Service at 1.800.635.5267 to purchase *DataFlow*™ Data Management Software.

System Configuration

The Renaissance II Spirometry System offers a wide range of configuration options that allow you to customize the operation and printed reports. The Renaissance II is preset at the factory with a default configuration. These settings can be easily changed. This section describes each configuration option.

To view or change configuration settings:

1. From the "*MAIN*" screen, press *9* on the key pad or scroll to *SETUP* using the cursor key and press *ENTER*.
2. Press the appropriate number on the key pad or scroll to the item whose options you want to change, and press *ENTER*. The current configuration and options are displayed.
3. Use the cursor arrow to tab to the selection. Enter the desired setting and press *ENTER*. You may change other settings or return to the "*SETUP*" menu by selecting *DONE*. When you have completed all of your changes, select *DONE* to return to the "*MAIN*" screen.

The following sections describe each configuration option and the choices for each option:

Spirometry Options (1)

Interpretation: The interpretation option determines whether the displayed and printed reports will include a computer generated interpretation. If you choose to include interpretations, you can select either the ATS or Enright algorithms for spirometry tests.

NOTE: The patient's height, birth date, and gender must be entered or no interpretation will be displayed.

Adult Normals: This configuration determines which set of equations will be used to generate the predicted values for patients 18 to 99 years of age. These predicted values appear on the display and printed reports and are used to derive the percent of predicted and the interpretation. The options are Knudson (1983), Morris, Knudson (1976), Crapo/Morris, and NHANES III. The option chosen will appear on each printed report. For the specified equations and references, see the *Predicted Normal Equations and References* section starting on page 60.

Pediatric Normals: This configuration determines which set of equations will be used to generate the predicted values for patients 4 to 17 years of age. These predicted values appear on the display and printed reports and are used to derive the percent of predicted and the interpretation. The options are Hsu, Polgar, Dockery, and NHANES III. The option chosen will appear on each printed report. For the specific equations and references, see the *Predicted Normal Equations and References* section starting on page 60.

Reproducibility: Turning this option on displays the number of reproducible tests performed by the patient when the SUMMARY option is selected from the VIEW menu, or when a report is printed.

Acceptability: Turning this option on displays the number of acceptable tests performed by the patient when the SUMMARY option is selected from the VIEW menu, or when a report is printed.

Best Criteria: This setting determines how the values for the best test are chosen. The three options are: "Val", "Sum", and "Enright." The definition of each option is as follows:

Val — includes the best values of FVC and FEV1 from any acceptable test. The remainder of the values will be taken from the maneuver with the highest sum of the FVC and the FEV1.

Sum — uses the values of FVC and FEV1 for the single maneuver with the highest sum of the FVC and the FEV1.

Enright — uses the values of the single test with the highest sum of the FVC, the FEV1, and 1/2 PEF.

NOTE: The "Val" (best value) method is recommended by the American Thoracic Society and mandated by NIOSH/OSHA standards and should be used for all industrial and disability testing.

QC Grades: This setting determines whether the display and printed reports (Best and Best 3 only) will include the test quality grades. The grades for FVC/FEV1 and FEV6/FEV1 tests are useful in judging the reliability of a particular test and for evaluating and improving the coaching abilities of test technicians. The test grades are A, B, C, D, and F. For specific grading criteria used by the Renaissance II, refer to the *Grading Criteria* section on page 44.

Lung Age: If the lung age calculation option is enabled and the patient's smoking history has been entered, the patient's lung age will be calculated. (See *Lung Age Interpretation* on page 47, for more information on lung age.)

COPD Risk: If the COPD risk option is enabled and the patient's smoking history has been entered, the risk of COPD will be calculated. (See *Risk of COPD* on page 47, for more information.)

Values Soft Key: By pressing the *VALUES* soft key, you can choose which spirometry parameters you want to include on printed reports where you have specified the User Defined format in the Print options (see *Print Options (3)* on page 80). If you have previously specified the Clinical or Industrial print option, and you select any or all of the following parameters, the print option automatically changes to User Defined: FEV3, FEF25-75, FET, FEF25, PEF, FEF50, PIF, FEF75, FEF50/FIF50.

Device Options (2)

Custom Header: This configuration allows you to generate a custom header on each page of the printed report. The custom header will appear centered at the top of each page. The header can consist of up to two lines and each line can have up to 20 characters.

Units: When non-metric units are selected, the patient's height is reported in inches (in.), the patient's weight is reported in pounds (lbs.), the elevation is reported in feet (ft.), and the ambient temperature is reported in degrees Fahrenheit (F). When metric is selected, the units used are centimeters (cm.), kilograms (kg.), meters (m) and degrees Celsius (C).

PEF Units: This configuration determines which units will be used when displaying peak expiratory flow. The options are liters/second (L/S) and liters/minute (L/M).

Clock: This setting determines how the time is entered and reported. The time format options are twelve hour (a.m./p.m.) or twenty-four hour.

Audio: If this option is enabled, an audible beep will sound when any key is pressed.

Audio Incentive: This setting allows you to activate or suppress the audio incentive that is heard during the patient's effort. The audio incentive feature can help the patient and technician achieve better test results.

Offset Curves: This setting allows you to choose how curves will be positioned on the grid. If you disable the offset curves option, all of the curves will be superimposed on one another and will begin at the zero point of the grid. If you enable the offset option, all of the curves will be offset from one another. The flow-volume curves will be offset by one liter and the volume-time curves will be offset by one second. This selection will affect the graph sizes. Pre/post-medication comparison graphs will not be offset.

Print Options (3)

Printer: The Renaissance II Spirometry System operates with a variety of parallel printers that use the Hewlett Packard graphic languages, as well as several other printer protocols. The following list indicates some of the printer types that are supported. Contact Puritan Bennett Technical Support for the printers and model numbers currently supported.

- HP DJ Black & White, Color, and Laser
- Epson Black & White, Color
- Canon Black & White

Paper: This setting allows you to choose the printer paper size. The options are 8.5"x 11" or A4 (International Standard paper size).

Format: You can choose between Clinical, Industrial, or User Defined formats for printing test results. Table 12 shows the information printed for each test performed. If you select either the Clinical or Industrial print option, and later change the marked selections using the *VALUES* soft key in Spirometry Options (see *Spirometry Options (1)* on page 78), the print format will automatically change to User Defined.

Table 12: Printed Values for Specified Print Format Options

Test Performed	*Print Format Option*		
	Clinical	*Industrial*	*User Defined*
FVC	FVC, FEV1, FEV1%, FEF25-75, FET, PEF	FVC, FEV1, FEV1%	FVC, FEV1, FEV1%, FEV3*, FET*, PEF*, FEF25-75*, FEF25*, FEF50*, FEF75*
FVL	FIVC, PIF, FEF50/ FIF50%	FIVC	FIVC, PIF*, FEF50/FIF50%*
MVV	MVV, MVV Rate	MVV, MVV Rate	MVV, MVV Rate
SVC	SVC	SVC	SVC
FEV6	FEV6	FEV6	FEV6
	* Any or all of these items may be specified in a User Defined report.		

Accept Msgs: Turning this option on will print the acceptability messages displayed during an FVC or FEV6 test, provided that the last test is selected for printing.

Interpretation: Enabling this option will print the computer generated interpretation in the report according to the configuration in Spirometry options (see *Spirometry Options (1)* on page 78).

Predicteds: This setting determines how predicted graphical data will appear on the printed graphs. The intent of the predicted graphical data is to produce a graphic reference of the patient's predicted values. The options are curve, points, or none. If you choose the curve option, a simulated Flow-Volume or Volume-Time curve will be plotted using predicted data. If you choose the points option, the individual data points appear on the grid as small blocks.

The following predicted points are plotted on each graph:

Flow-Volume Graph	*Volume-Time Graph*
PEF	FEV0.5
FEF25	FEV1
FEF50	FEV3
FEF75	FVC or FEV6
FVC or FEV6	

Graph: The graph format setting allows you to choose which graphs will appear on the printed reports. The options are: both (prints both volume-time (VT) and flow-volume (FV) graphs), volume-time (VT), flow-volume (FV), or none.

Grid: This setting determines whether there will be grid lines on the graphs. The grid lines may make it easier to read test values from the curves. The grid lines are required for disability testing.

Size: The graph size setting allows you to choose the size of graphs that appear on the printed report. The options are validation size and diagnostic size.

Validation size graphs are larger in scale and are designed to allow hand validation of test values. Due to its large size, a printed report with validation size graphs may require more than one page. All occupational and disability testing should use the validation size.

Diagnostic will usually allow the entire report to be printed on a single page, unless an SVC or MVV test is performed. Scaling information is printed with all graphs.

Scale: This setting determines whether to automatically scale the graph size up during printing, based on the size of the FVC/FVL curves stored (Auto option), or whether to leave the graph size fixed (1x option).

All Curves: Printing a Best or Best 3 report with this option turned on will show the best three flow-volume and volume-time graphs for each Pre-Med and Post-Med FVC/FVL and FEV6 maneuver performed in a patient's session. If this option is turned off, only the single best Pre-Med and Post-Med flow-volume and volume-time graph for FVC/FVL and FEV6 tests will print. If SVC and MVV maneuvers have been performed in the same session, only the single best Pre-Med and Post-Med curves are shown, regardless of whether the All Curves option is turned on or off. If there are no Post-Med tests, the three best FVC/VFL and FEV6 curves will print regardless of the All Curves option setting.

Settings (4)

Language: Allows you to select the language in which the information will be displayed and printed.

Date: Allows you to enter the day, month, and year using the numeric keypad.

Time: Allows you to enter the time using the numeric keypad. The time will display in 12-hr (am/pm) or 24-hr time depending upon your selection in the device setup (see *Device Options (2)*).

Elevation: This setting allows the user to enter altitude above sea level. The elevation is from 0-15,000 feet or 4572 meters. This setting allows the spirometer to determine the BTPS correction factor.

Display (5)

Autoscale Graphs: When this option is off, volume/time and flow/volume graphs are displayed at a fixed size. Turning this option on allows the display to automatically scale the volume/time and flow/volume graphs based upon the amount of stored data, up to twice the size of the fixed size graph.

Predicted: This setting allows you to choose how you want the unit to display predicted values on the screen. The options are curve, points, and none. See *Print Options (3)* for more information.

Show Patients By: This setting allows you to display patient data using the ID number or name entered during new patient setup.

NOTE: Setup locations 6, 7, and 9 are not used.

Storage (8)

Confirm Before Delete: Turning this option on requires the user to press the *YES* or *NO* soft key before patient records are deleted. See *Deleting Patient Data* on page 41 for more information.

Compress Curve Data: With this option enabled, graphical data is compressed so that memory capacity is approximately doubled.

The following table lists the factory defaults and possible settings for all configuration options:

Table 13: Setup and System Configurations

Configuration Option	*Factory Defaults*	*Alternate Settings*
Spirometry Options		
Interpretation	ATS	Enright, None
Adult Normals	Knudson 83	Morris, Knudson 76, Crapo/Morris, NHANES III
Pediatric Normals	Hsu	Polgar, Dockery, NHANES III
Reproducibility	ON	OFF
Acceptability	ON	OFF
Best Criteria	VAL	SUM, ENRIGHT
QC Grades	ON	OFF
Lung age	ON	OFF
COPD Risk	ON	OFF
Device Options		
Header	None	User-specified
Units	NON-METRIC (in, lbs, ft)	METRIC (cm, kg, m)
PEF Units	L/Sc	L/M
Clock	12 HR	24 HR
Elevation	0	0-15,000 ft.
Audio	ON	OFF
Audio incent	ON	OFF
Offset Curves	ON	OFF

Table 13: Setup and System Configurations (cont.)

Configuration Option	*Factory Defaults*	*Alternate Settings*
Print Options		
Printer	HP DJ B&W	HP DJ Col, HP Laser Epson B&W, Epson Col, Canon B&W
Paper	8.5" X 11"	A4
Format	Clinical	Industrial, User Defined
Accept Msgs	ON	OFF
Interpretation	ON	OFF
Predicteds	Curve	Points, None
Graph	Both	VT, FV, None
Grid	ON	OFF
Size	VAL	DIAG
Scale	1X	AUTO
All Curves	ON	OFF
Settings Options		
Language		
Date		
Time		
Elevation		
Display Options		
Autoscale Graphs	ON	OFF
Predicted	Curve	Points, None
Show Patients By	ID	Name
Storage Options		
Confirm Before Delete	ON	OFF
Compress Curve Data	ON	OFF

Printing the System Configuration

Perform the following steps to print the spirometer's setup and system configuration:

1. From the "*MAIN*" screen press *6* on the keypad or use the cursor arrow key to scroll to *PRINT* and press *ENTER*.
2. From the "*SELECT REPORT*" screen, press *3* on the keypad or use the cursor arrow key to scroll to *SETUP* and press *ENTER*. The configuration report is sent to the printer.

NOTE: Keep the System Configuration printout available for future reference. You may use it to return the Spirometer to its previous setup configuration if settings are changed.

Barometric Pressure vs. Altitude

Table 14: Barometric Pressure vs. Altitude

Altitude Feet → / ↓	0	100	200	300	400	500	600	700	800	900
	Barometric Pressure—mm Hg									
0	760	757	755	752	749	746	744	741	738	736
1000	733	730	728	725	722	720	717	714	712	709
2000	707	704	702	699	696	694	691	689	686	684
3000	681	679	676	674	671	669	666	664	661	659
4000	656	654	652	649	647	644	642	640	637	635
5000	632	630	628	625	623	621	618	616	614	611
6000	609	607	605	602	600	598	595	593	591	589
7000	586	584	582	580	578	575	573	571	569	567
8000	565	562	560	558	556	554	552	550	548	545
9000	543	541	539	537	535	533	531	529	527	525
10000	523	521	519	517	515	513	511	509	507	505
11000	503	501	499	497	495	493	491	489	487	485
12000	483	482	480	478	476	474	472	470	468	467
13000	465	463	461	459	457	456	454	452	450	448
14000	447	445	443	441	439	438	436	434	432	431
15000	429									

The above values are estimates only. Weather can change these values by ± 20 mmHg. Thus, this table does not replace a barometer.
(mmHg ≅ Torr; 1 ft = 0.3048 m; 1 m = 3.281 ft)

Reference: 1984: *Intermountain Thoracic Pulmonary Function Testing* Second Edition; pg. 183 (Smithsonian 1963, Iribarne 1973)

Reading the Barometric Pressure vs. Altitude Chart

The barometric pressure at your elevation can be read to the nearest 100 feet using the chart above. The following example shows how to find the barometric pressure at an altitude of 4700 feet:

1. Find the row corresponding to 4000 feet in the *vertical* altitude column at the left side of the graph.
2. Find the column corresponding to 700 feet in the *horizontal* altitude row at the top of the graph.
3. Read the barometric pressure (640 mm Hg) at the point where the row and column intersect.

Glossary of Medical Terminology

ATPD - Ambient temperature, pressure, dry.

ATPS - Ambient temperature, pressure, saturated with water vapor.

ATPS to BTPS Conversion Factor - A factor used to convert flow and volume data from values measured at ambient temperature (ATPS) to body temperature (BTPS).

ATS - American Thoracic Society. *(http://www.thoracic.org)*

Back Extrapolated Start Time - In order to measure the timed parameters more accurately and consistently, the ATS recommends using a technique called back extrapolation to determine the start of maneuver. The Renaissance II spirometer uses this technique. For more details, please reference "Standardization of Spirometry-1994 Update, ATS".

BTPS - Body temperature (37°C), pressure, saturated with water vapor.

CSA - Canadian Standards Agency.

Extrapolated Volume - The amount of air exhaled prior to the back-extrapolated start time. If this volume is more than 5% of the FVC, the maneuver started too slowly. This is also known as BEV (Back Extrapolated Volume).

FEF 25-75 - The mean flow rate between 25% and 75% of the Forced Vital Capacity. This is also known as MMEF (Mean Mid Expiratory Flow).

FEF50/FIF50% - Ratio of Forced Expiratory Flow at 50% of FVC to Forced Inspiratory Flow at 50% of FIVC.

FET - Forced Expiratory Time measured in seconds - The time from the beginning of the maneuver until the time at which highest volume was achieved during an FVC maneuver.

FEV0.5 - Forced Expiratory Volume measured in one half second (liters) - The volume of air exhaled in first half-second of an FVC maneuver.

FEV1 - Forced Expiratory Volume measured in one second (liters) - The volume of air exhaled in the first second of an FVC maneuver.

FEV1% - The ratio of FEV1 to FVC, expressed as a percentage. Also called FEV1/FVC%.

FEV3 - Forced Expiratory Volume measured in three seconds (liters) - The volume of air exhaled in the first three seconds of an FVC maneuver.

FEV6 - Forced Expiratory Volume measured in 6 seconds (liters) - The volume of air exhaled in the first six seconds of an FVC maneuver. Sometimes used as a surrogate for FVC.

FIVC - Forced Inspiratory Vital Capacity measured in liters -The maximum volume of air inspired with maximum effort after a complete exhalation.

Flow-Volume Curve - A graphic printout of an FVC/FVL maneuver plotting flow vs. volume.

FVC - Forced Vital Capacity measured in liters - The maximum volume of air exhaled as rapidly, forcefully and completely as possible from the point of maximum inhalation.

FVL - Flow Volume Loop- an FVC maneuver that is immediately followed by a maximal inspiration.

HIPAA - Health Insurance Portability and Accountability Act of 1996.

LLN - Lower Limit of Normal - The point which is considered to be the lower limit of the normal patient population for a given parameter. This point is defined in the various referenced studies.

MVV - Maximal Voluntary Ventilation measured in liters/min - The volume of air that can be exhaled during twelve seconds of rapid, deep breathing. The actual volume is extrapolated to one minute.

NIOSH - The National Institute for Occupational Safety and Health - A government agency established by the Occupational Safety and Health Act of 1970. NIOSH is part of the Centers for Disease Control and Prevention (CDC) and is the only federal institute responsible for conducting research and making recommendations for the prevention of work-related illnesses and injuries. *(http://www.cdc.gov/niosh/homepage.html)*

Obstructive Disease - Obstructive diseases are characterized by reduced air flow rates making it more difficult to move air into and out of the lungs. These diseases often result in a lowered FEV1 and FEV1 or FVC1%. Three of the most common diseases include asthma, chronic bronchitis and emphysema.

OSHA - Occupational Safety and Health Administration - A government agency that enforces laws and regulations in the workplace in regard to occupational safety and health hazards.

PEF - Peak Expiratory Flow Rate - measured in liters/sec or liters/min. Also called FEF max. or PEFR.

PIF - Peak Inspiratory Flow Rate - measured in liters/sec. Also called FIF max.

Restrictive Disease - These diseases are characterized by reduced lung volume or impaired movement of the lungs. A lowered FVC with normal FEV1 and FEV1/FVC or FEV% is often an indication of restrictive disease, although a poor patient effort is also a common cause of lowered FVC. Restrictive disease includes gross obesity, lung fibrosis, neuromuscular disease, or paralysis, as well as several occupational related diseases, such as pneumoconiosis and “cotton-dust lung.”

RR - Respiratory Rate or BPM (Breaths Per Minute)- The frequency of breaths during an MVV maneuver. Also called the MVV Rate.
SVC - Slow Vital Capacity - The total amount of air that can be slowly exhaled from full inspiration. Also called the Vital Capacity or VC.

Undetermined – An interpretation result generated by the Renaissance II when the FVC and FEV1 are greater than 100% and FEV1% is less than 100% of the predicted values.

VC - Vital Capacity (Same as SVC).

Volume-Time Curve - A graphic printout of an FVC and SVC or MVV maneuver showing volume vs. time.

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Notes

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